UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES of AMERICA, STATE OF ALASKA, STATE OF ARKANSAS, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, DISTRICT OF COLUMBIA, STATE OF FLORIDA, STATE OF GEORGIA, STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA. STATE OF IOWA, STATE OF LOUISIANA, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NEW YORK, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, STATE OF VERMONT, COMMONWEALTH OF VIRGINIA, STATE OF WASHINGTON, STATE OF WISCONSIN, and CITY OF CHICAGO, *ex rel.* JOSEPH CALIGUIRE, Plaintiffs and Relator,	Civil Case No. 18 CV 3451 PAM/BRT **COMPLAINT** **FILED IN CAMERA UNDER SEAL PURSUANT TO FALSE CLAIMS ACT 31 U.S.C. § 3730(b)(2)**

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

v. UPSHER-SMITH LABORATORIES, LLC, Defendant.	

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

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FALSE CLAIMS ACT COMPLAINT

NOW COMES Joseph Caliguire, Plaintiff Relator, through his attorneys, Cross Law Firm, S.C., by Nola J. Hitchcock Cross and local counsel Halunen Law, by Susan M. Coler, and states that this is an action brought on behalf of the United States of America by Relator Joseph Caliguire against Defendant Upsher-Smith Laboratories, LLC, for treble damages and civil penalties arising from Defendant's fraudulent conduct in violation of the federal civil False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA") and on behalf of the above-captioned States under the following statutes: Alaska, AS 09.58.010 *et seq.*; Arkansas, Ark. Code Ann §20-77-901 *et seq.*; California, Cal. Gov't. Code §12650 *et seq.;* Colorado, Colo. Rev. Stat. §25.5-4-304 *et seq.*; Connecticut, Conn. Gen. Stat. §176-301a *et seq.;* Delaware, Del. Code Ann. Title 6 §1201 *et seq.*; District of Columbia, D.C. Code Ann. §2-308.13 *et seq.*; Florida, Fla. Stat. §68.081 *et seq.*; Georgia, GA. Stat. Ann. §49-4-168 *et seq.*; Hawaii, Haw. Rev. Stat. §661-21 *et seq.*; Illinois, 740 ILCS 175/1 *et seq.*; Indiana, Ind. Code §5-11-5.5-1 *et seq.*; Iowa, Iowa Code §685.1 *et seq*; Louisiana , La. Rev. Stat. Ann. §46-437.1 *et seq.*; Maryland, Md. Code Ann. Health-Gen. §2-601 *et seq.;* Massachusetts, Mass. Gen. Laws Ch. 12 §5A *et seq.*; Michigan MCL 400.601 *et seq.*; Minnesota, Minn. Stat. §15C.01 *et seq.*; Montana, Mon. Code Ann. §17-8-401 *et seq.*; Nevada, Nev. Rev. Stat. §357.010 *et seq.*; New Jersey, N.J. Rev. Stat. §2A:32C-1 *et seq.*; New Mexico, N.M. Stat. Ann. §27-14-1 *et seq.*; New York, NY State Fin. Law Ch. §187 *et seq.*; North Carolina, NC. Gen. Stat. Ann. §1-605 *et seq.*; Oklahoma, Okla. Stat. tit. 63 §5053.1 *et seq.*; Rhode Island, R.I. Gen. Laws §9-1.1-1 *et*

seq.; Tennessee Tenn. Code Ann. §71-5-181 *et seq.*; Texas, Tex. Hum. Res. Code Ann. §36.001 *et seq.*; Vermont, 32 V.S.A. § 632 *et seq.*; Virginia Va. Code Ann. §8.01-216.1 *et seq.*; Washington, RCW §74.66.020 *et seq.*; Wisconsin, Wis. Stat. §20.931 *et seq.*; Chicago § 1-22-030 (collectively "the FCA States, "State False Claims Acts," or "State FCAs") for knowingly causing the submission of false claims for payment to the United States of America and the States' Medicaid programs. Caliguire also brings this action on behalf of himself to obtain a Relator share of the damages to the United States and above-captioned States, and for damages pursuant to 31 U.S.C. §3730(h) and Minn. Stat. §15C.145 for retaliatory failure to promote Relator to a higher-paying position.

I. INTRODUCTION TO THE FRAUD

1. This case involves two schemes by generic drug maker Defendant Upsher-Smith Laboratories, LLC to defraud the government and risk harm to patient-Beneficiaries covered by government healthcare plans including Medicare and Medicaid by creating adulterated drugs and then falsifying documentation to cover up its violations.

2. First, Defendant Upsher-Smith Labs violates the Food, Drug and Cosmetics Act ("FDCA") by repudiating the federally-mandated current Good Manufacturing Practices ("cGMP") that require vigilant cleaning, maintenance, and proper storage of medicinal fabricating equipment to prevent adulteration of medications.

3. Second, Defendant Upsher-Smith Labs systematically falsifies documents to conceal its cGMP violations and thereby causes the introduction of adulterated drugs into interstate commerce, where the drugs were ultimately consumed by government-

Beneficiaries and the medications are then paid for by Medicare, Medicaid, and other government-funded healthcare programs.

4. Since its creation through the 1984 passage of the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, the market for generic pharmaceuticals, which are drugs launched and marketed after patents expire for their chemically identical, but more expensive, branded counterpart, has grown into multi-billion- dollar industry.

5. Indeed, the global generic drugs market was valued at around $ 244.5 Billion in 2017, reflecting nearly 10% growth since 2010. Zion Market Research, *Global Generic Drug Market Size & Share to Reach $380.60 Billion by 2021*, March 21, 2018, *available at* https://globenewswire.com/news-release/2018/03/21/1443577/0/en/Global-Generic-Drug-Market-Size-Share-to-Reach-380-60-Billion-by-2021-Zion-Market-Research.html.

6. Generic drugs now reflect over 85% of all prescriptions, compared to just 50% in 2005.

7. Simply put, to save money and despite the risk of the potential patient harm, Defendant Upsher-Smith Labs knowingly operates a contaminated drug manufacturing plant.

8. Defendant systematically refuses to regularly clean the equipment used to formulate its pharmaceutical products. Augers, mixers, granulators, pumps, and other equipment are all used to make one drug after the other, without the required "major" and

"minor" intervening cleanings. At the direction of senior management, Defendant then falsely documents that cleanings have actually been conducted as legally required.

9. Moreover, when Defendant Upsher-Smith Labs does engage in any cleaning of its medication-formulation equipment, Defendant merely goes through the motions without any care whatsoever to potential patient harm: *Defendant performs such "cleaning" using sanitation equipment which itself has not been properly cleaned and had been left contaminated.* Again, Defendant Upsher-Smith Labs falsifies its records regarding the cleaning it does do— it fraudulently documents that the "cleaning" was properly conducted, although it was not, since contaminated "cleaning" equipment was used.

10. As described in detail below, any drugs manufactured in violation of the cGMPs are deemed "adulterated," regardless of whether or not the violation actually resulted in a harmful contamination. *See* 21 U.S.C. §§ 351(a)(2)(A) and(B).

11. Relator personally observed and reported to Defendant's management the continuous, widespread contamination of millions of doses of two of Defendant Upsher-Smith Labs' most commonly prescribed generic products: potassium chloride tablets and cholestyramine.

12. Rather than remove and repair or replace a defective machine, Defendant Upsher-Smith Labs allowed toxins from melted plastic and Teflon to leak into the hydrogenated vegetable oil solution used as filler in potassium chloride tablets and then intentionally omitted this manufacturing "deviation" from FDA-mandated

documentation, falsifying the documentation so that it appears to assure that no adulteration had taken place.

13. Potassium chloride is a commonly prescribed electrolyte replenisher used to treat hyponatremia, an electrolyte deficiency especially prevalent in frail, older patients suffering from osteoporosis, impaired balance, falls, hip fractures, cognitive dysfunction, or failure to thrive.

14. Similarly, rather than properly vacuum a large auger to prevent excess moisture from being absorbed into the product, Defendant Upsher-Smith skips and falsely documents the completion of this critical step when formulating cholestyramine, a bile acid sequestrant used to lower cholesterol that is prescribed to seniors on a wide-spread basis.

15. The above examples, as described in detail below, are two illustrative manifestations of what Relator has personally observed to be a longstanding corporate culture of cutting corners when it comes to cGMP compliance. Defendant's management directives result in failures to perform required cleaning of its drug formulation equipment and in falsification of documentation so that it appears that Defendant has not manufactured adulterated its drugs.

16. By operation of law, Defendant Upsher-Smith Labs' generic drugs are deemed adulterated.

17. Relator's information and understanding is that Defendant Upsher-Smith Labs' failure to comply with cGMP requirements and its falsification of its cleaning

records, was not confined to the area in which Relator specifically worked; rather it is a corporate-wide policy and practice.

18. Defendant Upsher-Smith Labs also introduces numerous other drugs into interstate commerce for sale to Government healthcare program patient-Beneficiaries, including but not limited to branded epilepsy medication and anti-seizure drugs Qudexy® and Topiramate and testosterone gel Vogelxo®, as well as generic Parkinson's medication amantadine, generic heart medication bumetanide, generic seizure medication clobazam, and generic Controlled Substance Act, Schedule II painkiller, morphine sulfate.

19. Such adulterated drugs sold to government Beneficiaries not only defraud State and Federal governments of their precious and limited health care dollars, but also put such Beneficiaries at significant risk of resulting health complication, potentially costing the Taxpayers even more to correct the problems that the adulterated drugs may have caused.

II. STATEMENT OF THE CASE

20. Relator Joseph Caliguire, brings this *qui tam* action on behalf of the United States of America and the FCA States for treble damages and civil penalties arising from Defendant Upsher-Smith's fraudulent conduct in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA") and the State FCAs involving claims caused to be made to, and paid by, the Government's healthcare programs, including Medicare and Medicaid, for prescription medications manufactured by Defendant.

21. This is a *qui tam* action against Defendant Upsher-Smith Labs to recover damages and civil penalties on behalf of the United States of America and the State of Minnesota arising from the false and/or fraudulent records, statements, and claims made or caused to be made in support of claims for payment by Government Healthcare Programs.

22. As introduced in Section I above and described in detail below, Defendant Upsher-Smith Labs engaged in and continues to engage in violation of cGMP standards and thereby has knowingly caused (1) claims for payment to medical providers who were recipients of Government funds and which payments were used to administer and advance the Medicare and Medicaid programs, (2) subsidies to be paid by Government to the States through the Medicaid program and (3) claims for payment through the Minnesota Medicaid program.

23. The pervasive knowing fraudulent conduct described herein began at least six years before the filing of this complaint and continues to the present with no sign of abatement despite Relator's repeated efforts to stop the fraud by actively opposing it to Defendant's management.

24. Relator also seeks damages for 31 U.S.C. §3730(h) and Minn. Stat. §15C.145 for retaliatory failure to promote him to a higher-paying position for which he was well-qualified.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

III. FEDERAL JURISDICTION AND VENUE

25. The acts prohibited by 31 U.S.C. § *3729 et seq.* and set forth with particularity herein occurred in Plymouth, Minnesota. Therefore, the court has jurisdiction over this case pursuant to 31 U.S.C. § 3732(a) as well as under 28 U.S.C. § 1345. This court has supplemental jurisdiction over this case for the claims brought on behalf of the States pursuant to 31 U.S.C. § 3732(b) and/or 28 U.S.C. § 1367, inasmuch as recovery is sought on behalf of the United States.

26. Venue is proper in the District pursuant to 31 U.S.C. § 3732(a), and 28 U.S.C. § 1391(b) and (c), because the Defendants transact business in this District and one or more of the acts committed by the Defendants and prosecuted by 31 U.S.C. § 3729 occurred in this District.

27. Relator has provided previously to the Attorney General of the United States and the Attorney Generals for the States a statement of all material evidence and information related to the Complaint.

28. On or about November 13, 2018, Relator provided written and oral notice of his intent to file this action to the District of Minnesota's United States Attorney's Office.

IV. PARTIES

A. Relator

29. Joseph Caliguire is a citizen of the United States of America and a resident of the City of Elk River, State of Minnesota.

30. Based upon his independent and direct knowledge, Relator Caliguire, who worked for Defendant Upsher-Smith Labs from 2011 to 2018 as a Packager and Manufacturing Technician/Formulator, brings this action on behalf of the United States of America pursuant to 31 U.S.C. § 3730(b)(2) and on behalf of the State of Minnesota pursuant to 740 Minn. Stat. §§ 15C.05(a).

B. Government Plaintiffs

31. The United States of America is a sovereign country whose Department of Health and Human Services ("HHS") pays claims submitted or caused to be submitted to it by Defendant Upsher-Smith Labs through the Medicare program and, as shared with the State of Minnesota, the Medicaid Program. Relator brings this action on behalf of the United States of America pursuant to 31 U.S.C. § 3730(b)(1).

32. Relator also brings this action on behalf of the State of Alaska pursuant to AS 09.58.010 *et seq.* The State of Alaska, through its Department of Health & Social Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Alaska's Medical Assistance program (hereinafter referred to as "Medicaid").

33. Relator also brings this action on behalf of the State of Arkansas pursuant to Ark. Code Ann §20-77-901 *et seq.* The State of Arkansas, through its Department of Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Arkansas' Medical Assistance program (hereinafter referred to as "Medicaid").

34. Relator also brings this action on behalf of the State of California pursuant to Cal. Gov't. Code §12650 *et seq.* The State of California, through its Department of Health Care Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through California's Medicaid program.

35. Relator also brings this action on behalf of the State of Colorado pursuant to Colo. Rev. Stat. §25.5-4-304 *et seq.* The State of Colorado, through its Department of Health Care and Policy Financing pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Colorado's Medicaid program.

36. Relator also brings this action on behalf of the State of Connecticut pursuant to Conn. Gen. Stat. §176-301a *et seq.* The State of Connecticut, through its Department of Social Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Connecticut's Medicaid program.

37. Relator also brings this action on behalf of the State of Delaware pursuant to Del. Code Ann. Title 6 §1201 *et seq.* The State of Connecticut, through its Department of Health and Social Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Delaware's Medicaid program.

38. Relator also brings this action on behalf of the District of Columbia pursuant to D.C. Code Ann. §2-308.13 *et seq.* The District of Columbia, through its Department of Health Care Finance, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through the District's Medicaid program.

39. Relator also brings this action on behalf of the State of Florida pursuant to Fla. Stat. §68.081 *et seq.* The State of Florida, through its Department of Children and Families, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Florida's Medicaid program.

40. Relator also brings this action on behalf of the State of Georgia pursuant to GA. Stat. Ann. §49-4-168 *et seq.* The State of Georgia, through its Department of Community Health, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Georgia's Medicaid program.

41. Relator also brings this action on behalf of the State of Hawaii pursuant to Haw. Rev. Stat. §661-21 *et seq.* The State of Hawaii, through its Department of Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Hawaii's Medical Assistance Medicaid program.

42. Relator also brings this action on behalf of the State of Illinois pursuant to Illinois, 740 ILCS 175/1 *et seq.* The State of Illinois, through its Department of Healthcare and Family Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Illinois' Medicaid program.

43. Relator also brings this action on behalf of the State of Indiana pursuant to Ind. Code §5-11-5.5-1 *et seq.* The State of Indiana, through its Office of Medicaid Policy and Planning, pays claims submitted to it by Defendant Upsher-Smith Labs through Indiana's Medicaid program.

44. Relator also brings this action on behalf of the State of Iowa pursuant to Iowa Code §685.1 *et seq.* The State of Iowa, through its Department of Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Iowa's Medicaid program.

45. Relator also brings this action on behalf of the State of Louisiana pursuant to La. Rev. Stat. Ann. §46-437.1 *et seq.* The State of Louisiana, through its Department of Health, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Louisiana's Medicaid program.

46. Relator also brings this action on behalf of the State of Maryland pursuant to Md. Code Ann. Health-Gen. §2-601 *et seq.* The State of Maryland, through its Department of Health, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Maryland's Medicaid program.

47. Relator also brings this action on behalf of the Commonwealth of Massachusetts pursuant to Mass. Gen. Laws Ch. 12 §5A *et seq.* The Commonwealth of Massachusetts, through its Department of Health and Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Massachusetts' Medicaid program.

48. Relator also brings this action on behalf of the State of Michigan pursuant to Michigan MCL 400.601 *et seq.* The State of Michigan, through its Department of Health and Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Michigan's Medicaid program.

49. Relator also brings this action on behalf of the State of Minnesota pursuant to Minn. Stat. §15C.01 *et seq.* The State of Minnesota, through its Department of Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Minnesota's Medicaid program.

50. Relator also brings this action on behalf of the State of Montana pursuant to Mon. Code Ann. §17-8-401 *et seq.* The State of Montana, through its Department of Public Health and Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Montana's Medicaid program.

51. Relator also brings this action on behalf of the State of Nevada pursuant to Nev. Rev. Stat. §357.010 *et seq.* The State of Nevada, through its Department of Welfare and Supportive Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Nevada's Medicaid program.

52. Relator also brings this action on behalf of the State of New Jersey pursuant to N.J. Rev. Stat. §2A:32C-1 *et seq.* The State of New Jersey, through its Department of Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through New Jersey's Medical Assistance program (hereinafter referred to as "Medicaid").

53. Relator also brings this action on behalf of the State of New Mexico pursuant to N.M. Stat. Ann §§27-14-1 *et seq.* The State of New Mexico, through its Department of Human Services, pays claims submitted to it by Defendant Upsher-Smith Labs through New Mexico's Medicaid program.

54. Relator also brings this action on behalf of the State of New York pursuant to NY State Fin. Law Ch. §187 *et seq.* The State of New York, through its Department of Health, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through New York's Medicaid program.

55. Relator also brings this action on behalf of the State of North Carolina pursuant to NC. Gen. Stat. Ann. §1-605 *et seq.* The State of North Carolina, through its Department of Health and Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through North Carolina's Medicaid program.

56. Relator also brings this action on behalf of the State of Oklahoma pursuant to Okla. Stat. tit. 63 §5053.1 *et seq.* The State of Oklahoma, through its Health Care Authority, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Oklahoma's Medicaid program.

57. Relator also brings this action on behalf of the State of Rhode Island pursuant to R.I. Gen. Laws §9-1.1-1 *et seq.* The State of Rhode Island, through its Department of Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Rhode Island's Medicaid program.

58. Relator also brings this action on behalf of the State of Tennessee pursuant to Tenn. Code Ann. §71-5-181 *et seq.* The State of Tennessee, through its Division of TennCare, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Tennessee's Medicaid program.

59. Relator also brings this action on behalf of the State of Texas pursuant to Tex. Hum. Res. Code Ann. §36.001 *et seq.* The State of Texas, through its Department of Health and Human Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Texas' Medicaid program.

60. Relator also brings this action on behalf of the State of Vermont pursuant to Cite as: 32 V.S.A. § 632 *et seq.* The State of Vermont, through its Department of Vermont Health Access, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Vermont's Medicaid program

61. Relator also brings this action on behalf of the Commonwealth of Virginia pursuant to Va. Code Ann. §8.01-216.1 *et seq.* The Commonwealth of Virginia, through its Department of Medical Assistance Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Virginia's Medicaid program.

62. Relator also brings this action on behalf of the State of Washington pursuant to RCW §74.66.020 *et seq*. The State of Washington, through its Department of Social and Health Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Washington's Medicaid program

63. Relator also brings this action on behalf of the State of Wisconsin pursuant to Wis. Stat. § 20.931 (repealed July 12, 2015). The State of Wisconsin, through its Department of Health Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Wisconsin's Medicaid program.

64. Relator also brings this action on behalf of the City of Chicago pursuant to Chicago §1-22-030. The City of Chicago, through its Department of Health Services, pays claims caused to be submitted to it by Defendant Upsher-Smith Labs through Chicago's Medicaid program.

C. Defendant

65. Defendant Upsher-Smith Laboratories, LLC, is a Minnesota limited liability company with a principal place of business located at 6701 Evenstad Drive N, Maple Grove, Minnesota 55369.

V. APPLICABLE LEGAL AUTHORITY

A. False Claims Act

66. The False Claims Act ("FCA") was originally enacted during the Civil War. Congress substantially amended the Act in 1986, 2009, and 2010, to enhance the ability of the United States to recover losses it sustained as a result of its payment of fraudulent claims.

67. In 1986 Congressional hearings found that false claims for payment in federal programs were pervasive and that the FCA is a primary tool for combating false claims to the government. Accordingly, Congress amended the Act with the intention of enhancing incentives for individuals with knowledge of false claims against the Government to disclose the information without fear of reprisals. *See generally, False Claims Act Amendments: Hearings before the Subcomm. of Admin. Law and Gov't Relations of the Comm. on the Judiciary*, 99th Cong. 48 (1986).

68. The current FCA is designed to encourage the private bar to commit legal resources to pursuing fraud on the Government's behalf and to create a private/public partnership to obtain recovery for false claims submitted to the Government. *See generally, False Claims Act Amendments: Hearings before the Subcomm. of Admin. Law and Gov't Relations of the Comm. on the Judiciary*, 99th Cong. 48 (1986).

69. The FCA subjects a person to liability under section 31 U.S.C. §§3729 *et seq.* who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), … or
>
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government

70. Under 31 U.S.C. §§3729 (b)(1), the "terms 'knowing' and 'knowingly:'"

> (A) mean that a person, with respect to information—
>
> (i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information, and;

(B) require no proof of specific intent to defraud.

71. Any person who violates the FCA anti-retaliation provision is liable for reinstatement plus "2 times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys' fees." 31 U.S.C. §3730(h)(2).

72. After a catch-up inflation increase, the range of the civil penalties is adjusted for inflation by the annual cost-of-living-adjustment. Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Section 701 of the Bipartisan Budget Act of 2015, Public Law 114–74). For civil penalties assessed after February 3, 2017, whose associated violations occurred before November 2, 2015, the adjusted civil penalties are between $10,957 and $21,916 per violation, while civil penalties assessed after August 1, 2016, and on or before February 3, 2017, whose associated violations occurred after November 2, 2015, are between $11,181 and $22,363. 28 C.F.R. § 85.5.

73. Additionally, 31 U.S.C. §3730(h) prohibits employers from discharging or otherwise discriminating against employees in the terms and conditions of their employment "because of lawful acts done by the employee…in furtherance of an action under this section or other efforts to stop 1 or more violations" of the FCA.

B. Current Good Manufacturing Practice Regulations

74. The Food and Drug Administration ("FDA") is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary dugs, biological products, medical devices, the nation's food supply, cosmetics, and products that emit radiation. The FDA administers, *inter alia*, the Federal Food, Drug and Cosmetics Act, "FDCA," §§ 301 *et seq*.

75. In addition to its approval processes for new and generic drugs, the FDA attempts to ensure the quality of drugs by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice ("cGMP") regulations.

76. Found in 21 C.F.R. Parts 210 and 211, the cGMPs contain the *minimum* requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations are designed to assure that the medication is pure, safe for use, and that it has the ingredients and strength as labeled.

77. As explained by FDA's former Deputy Associate General Counsel Eric M. Blumberg, the cGMPs reflect the fact that:

> … drug manufacturers occupy a virtual fiduciary relationship to the public ... FDA shares this trustee relationship to the consumer with industry leaders, but the initial and ultimate responsibility remains with those leaders. This is true not only because the law makes it so, but also for the practical reason that the FDA cannot be in every factory, much less monitor every decision that is made every day that affects the quality of our food and drugs.

Abbott Laboratories Consent Decree and Individual Responsibility Under the Federal Food, Drug and Cosmetic Act, 55 FOOD AND DRUG L.J., 145, 147. (Emphasis added.)

78. Thus, the cGMPs require pharmaceutical companies to meet *minimum* standards for manufacturing, processing, packaging, and holding drugs to assure that they meet the safety, identity, *strength*, quality, and *purity* characteristics that they purport to possess.

79. Manufacturers must demonstrate compliance with the cGMPs through written documentation of procedures and practices.

80. The cGMPs dictate, *inter alia*, standards for:

1) personnel engaged in quality control; the design, construction and maintenance of buildings and facilities;
2) the construction, cleaning and maintenance of equipment; the storage, inspection and testing of drug components and containers;
3) the control of production and process, including procedures for sampling and testing of in-process drug products for conformity with specifications and prevention of microbiological contamination; control of packaging, labeling, storage and distribution;
4) laboratory controls including testing of drug product batches for conformity with final specifications; and
5) the maintenance of records and reports and conducting of investigations and procedures for handling of returned and salvaged product.

81. Particularly relevant to Defendant Upsher-Smith Lab's conduct, as alleged in detail below, is 21 C.F.R. Part 211, subpart D, which contains cGMPs related to drug manufacturing equipment.

82. Under 21 C.F.R. § 211.67(a), equipment and utensils used to manufacture drugs "shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements. (Emphasis added.)

83. Additionally, under 21 C.F.R. § 211.67(b), manufacturers must establish and follow "written procedures …for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product."

84. "These procedures shall include, but are not necessarily limited to, the following:

(1) Assignment of responsibility for cleaning and maintaining equipment;

(2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;

(3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;

(4) Removal or obliteration of previous batch identification;

(5) Protection of clean equipment from contamination prior to use;

(6) Inspection of equipment for cleanliness immediately before use."

21 C.F.R. § 211.67(b).

85. Under 21 C.F.R. § 211.67(c), "[r]ecords shall be kept of maintenance, cleaning, sanitizing, and inspection."

86. Likewise, 21 C.F.R. § 211.100(a) require drug manufacturers to maintain "written procedures" not just for the cleaning of equipment, but also for all of its "production and process control[s] designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess."

87. Such controls include those required to ensure the integrity of the entire drug manufacturing process, e.g. the proper processing of drug ingredients (called "components), 21 C.F.R. § 211.101, the calculation of the overall "yield" of each drug "batch," 21 C.F.R. § 211.103, the identification of equipment, 21 C.F.R. § 211.105; the sampling and testing of "in-process materials and drug products," 21 C.F.R. § 211.110; and, the recording, [w]hen appropriate," of "time limits for the completion of each phase of production." 21 C.F.R. § 211.1111.

88. Under 21 C.F.R. § 211.100(b), "[a]ny deviation from the written procedures shall be recorded and justified."

89. Finally, under 21 C.F.R. § 211.192, "[a]ll drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the [manufacturer's] quality control unit to determine compliance with all

established, approved written procedures before a batch is released or distributed. Discrepancies must be "thoroughly investigated" and documented, with a "written record of the investigation" including its "conclusions and follow-up."

90. Drugs are deemed to be adulterated if they are not manufactured in compliance with the above cGMPs or if they are contaminated. 21 U.S.C. §§ 351(a)(2)(A); (B); 21 C.F.R. § 210.1.

91. It is a violation of the FDCA, 21 U.S.C. §§ 31(a), to directly or indirectly cause adulterated drugs to be introduced or delivered for introduction into interstate commerce.

92. Payment for Medicare claims is made by the United States through CMS. In turn, CMS contracts with private insurance companies to receive, review, and pay appropriate claims for prescription drugs. 42 U.S.C. § 1395w-101 *et seq.*

C. The Medicare and Medicaid Program

93. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, enacted in 1965, established the Health Insurance for the Aged and Disabled Program, commonly referred to as the Medicare Program. Pursuant to the Medicare program and other government healthcare programs described below, the government pays claims for certain medical services for persons age 65 and older, and for persons with disabilities. 42 U.S.C. § 1395w.

94. Medicare pays health care providers for the reasonable costs of providing covered health services to Medicare beneficiaries. 42 U.S.C. § 1395x(v)(1)(A).

95. The United States Department of Health and Human Services ("HHS") is responsible for the administration and supervision of the Medicare program. The Center for Medicare and Medicaid Services ("CMS") is the division of HHS directly responsible for the administration of Medicare.

96. Medicare has multiple parts:

A) Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services, hospice services and related care.

B) Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of physicians' services and outpatient diagnostic tests.

C) Medicare Part C, the Medicare Advantage program, covers both Part B and C and can cover additional services through plans administered by private insurance companies.

D) Medicare Part D, the Medicare Prescription Drug Benefit, at issue herein, covers the costs of prescription drugs and is also available as part of Part C Medicare Advantage plans.

97. Payment for Medicare claims is made by the United States through CMS. In turn, CMS contracts with private insurance companies to receive, review, and pay appropriate claims for prescription drugs. 42 U.S.C. § "1395w-101 *et seq.*

98. The Federal Government administers other health care programs including, but not limited to, TRICARE/CHAMPUS, CHAMPVA, Medicaid and

federal workers' compensation programs, all of which have suffered false claims at the hands of the Defendants.

99. TRICARE/CHAMPUS, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. 10 U.S.C. §§ 1071 *et seq.*; 32 C.F.R. § 199.4(a).

100. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability. 38 U.S.C. §§ 1781 *et seq.*; 38 C.F.R. § 17.270(a).

101. The Medicaid Program ("Medicaid"), administered by individual states and jointly funded by State and Federal taxpayer revenue, is a health insurance program also created as part of the Social Security Act, 42 U.S.C. §§ 1396-1396v.

102. The federal portion of a state's Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's *per capita* income compared to the national average. 42 U.S.C. § 1396d(b)

103. The FMAP constitutes approximately 50% of the cost of the States' respective Medical Assistance Programs.

104. The Federal Employees' Compensation Act provides workers' compensation coverage, including coverage of medical care received as a result of a workplace injury, to federal and postal employees. The Act is administered by the Department of Labor, Division of Federal Employees' Compensation. 5 U.S.C. §§ 8101 et seq.; 20 C.F.R. §§ 10.0 *et seq.*

1. Payment of Drug Claims Under Medicare Part D

105. At all times relevant to this action, Defendant Upsher-Smith Labs' customers and the end-users of its pharmaceutical products respectively include retail pharmacies or pharmacy wholesalers; and Beneficiaries of government healthcare programs including Medicare Part D.

106. Medicare prescription drug benefits program known as Medicare Part D became effective January 1, 2006 as part of the Medicare Prescription Drug Improvement and Modernization Act of 2003. 42 U.S.C. § 1395w-101(a)(2).

107. The United States annually pays approximately 75 to 80 per cent of the cost of providing covered drugs to Medicare Part D Beneficiaries. However, the United States does not pay pharmacies or prescribers directly. Rather, the United States pays Medicare Part D Plan Sponsors, which are typically private insurance companies, to reimburse retail pharmacies, (referred to as "downstream entities" under 42 C.F.R. § 423.4 or "network pharmacies"), either directly or through contractors known as Pharmacy Benefit Managers ("PMBs").

108. Thus, when a pharmacy dispenses a drug to a Medicare Beneficiary, it submits an electronic claim to the Beneficiary's Part D plan and receives payment from the Part D Plan Sponsor for the price remaining after the Beneficiary pays his or her portion of the price of the prescription drug in the form of a "co-pay" or "coinsurance," generally a nominal amount.

109. In the pharmacy industry, the PBM third-party administrators typically act as intermediaries between retail pharmacies and insurers, facilitating the processing and payment of prescription drug claims, including the payment of reimbursement monies to pharmacies and the submission of cost data to the Government on behalf of the Part D Plan Sponsor.

110. Generally, PBMs and Part D sponsors enter into negotiated agreements with drug manufacturers like Defendant Upsher-Smith Labs, and the agreed-upon cost of the drugs are then entered into a multi-factor formula that determines the retail price of individual units of the drugs.

2. Payment of Drug Claims Under Medicaid

111. As described above, the Federal Government, through CMS, generally funds approximately 50% of the States' Medicaid programs, which is administered by the States' respective versions of the Department of Health and Human Services (HHS) and provides healthcare coverage for low-income, disabled, and/or elderly individuals. 42 C.F.R. § 433.15(b)(7).

112. For example, in Minnesota, this coverage includes hundreds of prescription brand-name and generic drug products. Some of these drugs—such as certain controlled substances or particularly expensive medications—require a "prior authorization," which is a written authorization issued by the Minnesota DHS to a provider prior to the provision of a service intended to safeguard against unnecessary or inappropriate care and services. *See* 740 Minn. Stat. §§ 256B.0625 sub. 13 f.

113. In addition to its 50% contribution to the administration of Medicaid costs, the Federal Government, through CMS, administers the Medicaid Drug Rebate Program ("MDRP") whereby drug manufacturers enter into national rebate agreements with the Secretary of the Department of Health and Human Services (HHS) in exchange for state Medicaid coverage of most of their drugs. 42 C.F.R. § 447.509. Under the MDRP, drug manufacturers are required to submit detailed, drug-specific product and pricing data to CMS in order to maintain Medicaid coverage. Once their drugs are covered by a state plan, manufacturers including Defendant Upsher-Smith Labs pay rebates on a quarterly basis to both the States and CMS to help offset the cost of the covered drugs. 42 C.F.R. § 447.510.

VI. FACTUAL BACKGROUND

A. Defendant Upsher-Smith Lab's Corporate Structure

114. Founded in 1919 by English chemist and pharmacist Frederick Alfred Upsher Smith and initially focused on the cardiac benefits of the foxglove or digitalis plant, today Defendant Upsher-Smith Labs specializes in manufacturing generic drugs.

115. From 1981 to 2017, the Evenstad family owned Defendant Upsher-Smith Labs through their privately held holding company Acova, Inc., with Mark Evenstad as the Chief Executive Officer until May 31, 2017, and his father, Kenneth Evenstad, Chairman of the Board of Directors.

116. On June 1, 2017 the President of Upsher-Smith Labs, Rusty Field, replaced Mark Evenstad as Chief Executive Officer. Fields now holds both positions.

117. Defendant Upsher-Smith Labs' manufacturing operations are overseen by Senior Vice President of Operations Scott Denicourt, Senior Director of Operations John Koski, Operations Supervisor William Thompson, Operations Supervisor Gary Parker, Associate Director of Manufacturing Operations Amy Niesen, and Vice President of Global Sales Scott Hussey.

118. In addition to its corporate and administrative headquarters in Maple Grove, Minnesota, Defendant Upsher-Smith Labs maintains a "satellite office" in Morristown, New Jersey, primarily for its east coast sales personnel. In addition, Defendant Upsher-Smith Labs operates manufacturing plants in Plymouth, Minnesota and in Denver, Colorado.

119. At about 200,000 square feet, Defendant's Plymouth, Minnesota plant houses its most extensive manufacturing operations and it is the primary worksite of about 150 of its approximately 500 employees, including Relator Joseph Caliguire, who worked there during the period 2011 until September 2018.

120. Defendant Upsher-Smith Labs has patents on a its own branded drugs: Klor-Con® M, Qudexy® XR, Testosterone Gel, Topiramate ER, and Vogelxo®.

121. In addition, Defendant Upsher-Smith Labs manufactures more than 30 generic drugs. Defendant lists its full stable of manufactured drugs as follows:

AMANTADINE HCI Capsules, USP

AMANTADINE HCl Tablets

BACLOFEN Tablets, USP

BENAZEPRIL HCl and Hydrochlorothiazide Tablets

BETHANECHOL CHLORIDE Tablets, USP

BEXAROTENE CAPSULES

BUMETANIDE TABLETS, USP

CHLORPROMAZINE HCl Tablets, USP

CHOLESTYRAMINE for Oral Suspension, USP

CLOBAZAM Oral Suspension, CIV

CLOBAZAM Tablets, CIV

CLOMIPRAMINE Hydrochloride Capsules, USP

DIPHENOXYLATE HYDROCHLORIDE & ATROPINE SULFATE Tablets, USP, CV

DIVALPROEX SODIUM Delayed-Release Tablets, USP

DOXAZOSIN TABLETS, USP

EPLERENONE Tablets

EXEMESTANE Tablets

FERROUS SULFATE Enteric Coated Tablets, Dietary Supplement

Jantoven® Warfarin Sodium Tablets, USP

KLOR-CON® Powder (Potassium Chloride) for oral solution

MEMANTINE HYDROCHLORIDE Tablets

MIDODRINE HYDROCHLORIDE Tablets, USP

MORPHINE SULFATE Extended-release Capsules, USP, CII

NYAMYC® (Nystatin Topical Powder, USP)

OXANDROLONE Tablets, USP, CIII

OXYBUTYNIN CHLORIDE Tablets, USP

PACERONE® (Amiodarone HCl) Tablets

POTASSIUM CITRATE Extended-Release Tablets

PREVALITE® Powder (Cholestyramine for Oral Suspension, USP)

Qudexy® XR (topiramate) Extended-Release Capsules

SORINE® (Sotalol HCl Tablets, USP)

Testosterone Gel, CIII

TOPIRAMATE Extended-Release Capsules

TRIFLUOPERAZINE HCI Tablets, USP

VALPROIC ACID Capsules, USP

Vandazole® (metronidazole vaginal gel, 0.75%)

Vigadrone® (vigabatrin) for Oral Solution

Vogelxo® (testosterone) gel, CIII

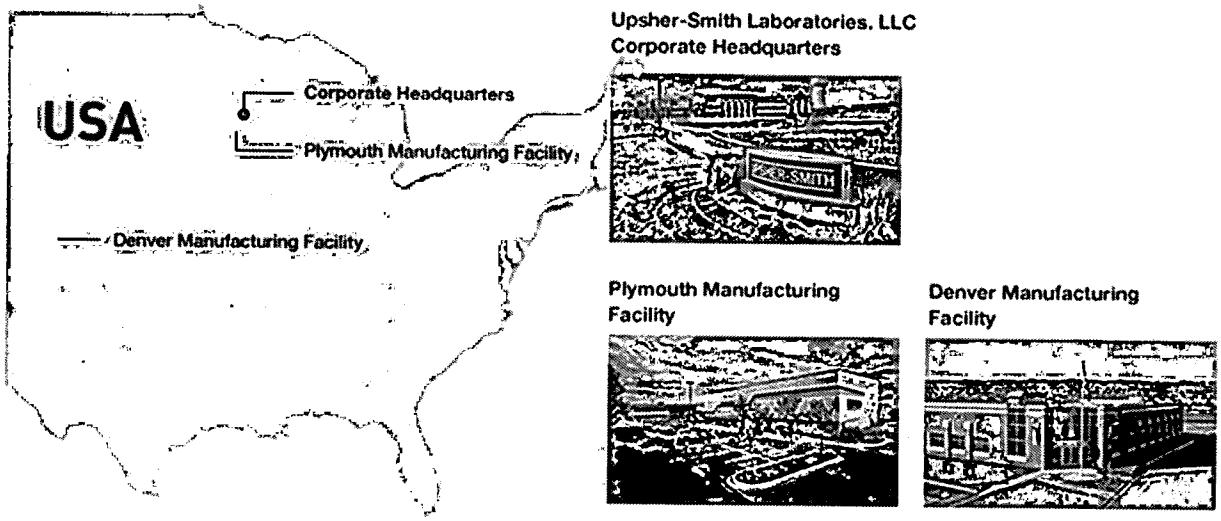
122. The majority of the drugs manufactured at Defendant's Plymouth, Minnesota plant involve the process of "compounding," or combining liquid and dry chemical ingredients using industrial "high-sheer" mixers, augers, and ribbon blenders.

123. In June 2017, in a $1 Billion deal, the publicly held Japanese generics manufacturer Sawai Pharmaceutical Co., Ltd. (Tokyo.4555) acquired Upsher-Smith Labs, leaving the Upsher-Smith Labs' management fully intact, while providing Sawai

Pharmaceutical Co., Ltd. with its first market foothold in the United States for the approximately 700 generic prescription drugs it manufactures.

124. Hiroyuki Sawai is the Chairman and Mitsuo Sawai is the President of Sawai Pharmaceutical Co., Ltd. which primarily provides central nerve system drugs, circulatory drugs, alimentary canal drugs, vitamin drugs, blood and body fluid drugs, metabolic medicinal products, allergy drugs, antibiotic agents and chemotherapy agents, among others. The Company distributes its products through sales companies, wholesale shops and other pharmaceutical manufacturers, among others.

125. On its website, Sawai Pharmaceutical Co., Ltd. now lists its operations in the United States, the only operations outside of Japan, as follows:



B. Defendant Upsher-Smith Labs' Operational Structure

126. Once the chemists, pharmacists, and engineers in Defendant Upsher-Smith Labs' Department of Research and Development determine the ingredients, or "components," of a particular drug, the physical manufacturing process begins in the

Department of Operations, at either the Plymouth, Minnesota plant or the Denver, Colorado plant.

127. Generally, Defendant's Department of Operations is made up Formulators, also known as Manufacturing Technicians, who physically mix or otherwise combine the chemical components of the drugs; Operators, who calibrate and utilize machinery involved in transporting the solutions and mixtures to and from the various steps in the manufacturing process; Packagers, who separate the finished product into saleable units; and Quality Associates, who are responsible for inspecting the final product as well as, ostensibly, for verifying that Formulators, Operators, and Packagers are performing their duties in compliance with the cGMPs.

128. Defendant Upsher-Smith Labs' manufacturing floor and operations are divided into "lines" and "batches," depending on which drug is scheduled to be manufactured, as ordered and scheduled by upper management in coordination with sales executives.

129. Defendant Upsher-Smith Labs' manufacturing floor hosts a wide variety of machinery, including augers, mixers, blenders, mills, feeders, trays, vats, granulators, tablet presses, capsule filling machines, coaters, totes, bins, turrets, scales, x-ray inspection systems, spray drying accessories, and other tools and accessories, all of which must be thoroughly cleaned, as more fully explained below, and all such cleanings must be performed and documented in order to maintain cGMP compliance.

130. To specify the nature of the required cleaning and to document each cleaning, Defendant Upsher-Smith Labs has developed a number of Standard Operating Procedures ("SOPs") which, among other factors, distinguish between "major" and "minor" cleans.

131. In order to document the cleaning, Defendant maintains a "Use and Clean Logbook" and a "Cleaning Checklist" for *each* piece of equipment and related SOP. The Log Book contains a chart that identifies the product and batch number for which the equipment was last used; the date of the last use and the date of the clean; the name of the employee who performed the clean; the name of the employee who "checked" or validated the clean; whether any maintenance was done subsequent to the clean; and whether the clean was "major" or "minor," as more fully explained below.

132. A typical shift at Defendant's Plymouth plant included about 10 Formulators working alongside approximately 6 Operators and as many as 30 Packagers under Operations Supervisor William Thompson.

C. Relator Joseph Caliguire

133. Plaintiff Relator Joseph Caliguire began his career with Defendant Upsher-Smith Labs in 2011 as a Packager.

134. In 2015, Defendant promoted Relator from Packager to Formulator, a position also referred to as Manufacturing Technician. As a Formulator, Relator's duties included assembling, using, and cleaning equipment involved in the manufacture of drugs.

135. During Relator's employment with Defendant, Relator raised many concerns with leadership regarding lack of oversight and control within the manufacturing facility, inadequate and deficient procedures, lack of proper training, and failure to comply with the cGMPs, in his attempt to stop Defendant Upsher-Smith Labs from submitting false claims.

136. Relator's employment with Defendant ended in September 2018.

D. The Competitive Generic Drug Business Environment

137. The competitive generic drug business environment in the United States and worldwide provides both the context and the motivation for Defendant's false claims at issue.

138. While increased healthcare costs have pushed government and third-party payors to increase spending on more affordable generic medications, this increase in sales has also led to "extreme price competition in the generic pharmacy market." George P. Ball *et al.*, *Product competition, managerial discretion, and manufacturing recalls in the U.S. pharmaceutical industry*. J. Operations Management, 2018, *at*, 10.1016/j.jom.2018.04.003.

139. In a comprehensive study of 939 recalls at 64 drug manufacturing companies over a 12-year period, researchers at Indiana University found that the companies producing a higher proportion of generic products face more product competition and have higher rates of Class 1 and Class 2 manufacturing recalls, the most

serious FDA recall designations applied when product defects could cause death or medically reversible harm to patients.

140. In addressing these startling findings, the study's co-author, Rachna Shah, associate professor of supply chain and operations at the University of Minnesota, explained that while generic drug manufacturers are not allowed to change the design of the product, they have considerable leeway regarding manufacturing decisions, which "may include reducing labor costs, hiring less experienced employees or lowering maintenance costs by servicing manufacturing equipment less often...." Science Dailey, *Price competition for generic drugs linked to increase in manufacturing-related recalls*, May 31, 2018, https://www.sciencedaily.com/releases/2018/05 /180531143035.htm.

141. The detailed facts below show, *inter alia*, that Defendant Upsher-Smith Labs made precisely the managerial decisions described in the above paragraph, including reducing labor costs, hiring less experienced employees, and lowering maintenance costs by servicing manufacturing equipment less often, as well as using contaminated storage areas, adding coating over tablets with visible contamination, and leaving drug residue in equipment when starting a run of new medication.

142. Indeed, Sawai Pharmaceutical Co., Ltd.'s website recognizes the tough pricing environment for generic drugs, addressing the issue as follows:

> *Strong Emphasis on Cost Controls*
>
> *Sawai believes the impact of NHI drug price reductions and heightened competition is likely to result in lower unit selling prices, even if sales volume increases. While committed to maintaining stable supply and high levels of quality, we are also focusing on controlling costs. This includes efforts to*

> *improve efficiency in production through manufacturing and sales tie-ups, diversifying business partners in areas such as raw materials, and conducting regular reviews in the terms of trade.*

143. In short, generic drug producers face intense pressure to cut corners in the manufacturing process, which increases the risk of adulteration of their drug products.

144. It is within the context of this highly competitive generic drug manufacturing environment, with its lowering unit selling prices and need to reduce drug production costs to stay competitive, that the false claims addressed in this complaint take place.

145. As described below, Defendant Upsher-Smith Labs has succumbed to this market and profit pressure since at least 2011 and, further, Defendant Upsher-Smith Labs has falsified the documentation of its cGMP compliance to hide the fraud and to avoid its detection by the FDA.

E. Defendant's History of cGMP Violations

146. Defendant Upsher-Smith Labs has a history of dangerous cGMP violations. In 2011, Defendant recalled over 20 different drug products manufactured between May 17, 2010 and November 17, 2010 after a bottle of Jantoven® Warfarin Potassium, USP, 3 milligram tablets was found to actually contain 10 milligram tablets, more than triple the labeled strength.

147. Notably, in a demonstration of its willful disregard for cGMP and to continue its false claims, Defendant did not make any material changes to its cGMP compliance practices and procedures following any of the 20 recalls.

148. Indeed, the 2010 failure of Defendant's Quality Assurance and Packaging Departments pales in comparison to the abject failure of the Formulator and Operator Departments, which include the personnel involved in the frontline production of the drug products using raw chemical ingredients, to maintain a safe and sterile manufacturing environment in documented compliance with 21 C.F.R. § 211.67.

149. Simply put, Defendant prevents its understaffed teams of Formulators and Operators from compliance, not only by its directives discussed in detail below, but also by its short-staffing. This makes it impossible for the Operators and Formulators to comply with cGMP cleaning and documentation requirements during their hours of work, thereby assuring non-compliance with cGMP.

F. Defendant's Managerial Directives and Its Culture of Retaliation

150. Because Defendant manufactures and sells its drugs in bulk, time spent per batch is carefully tracked to continuously reduce time spent on each drug batch in the manufacturing process.

151. Defendant's time tracking process is facilitated by use of a bar-coded document generated to record each distinguishable component of the overall manufacturing process for a given drug, known as a "Confirmation Slip."

152. The Confirmation Slip includes the name of the product, the batch number, a description of the process component, the "standard number of hours," and "standard number of employees" Defendant has assigned as necessary to complete the process. Next to these pre-determined hour allocations are blanks where Formulators and Operators

could manually record the "actual number" of hours and employees to complete the particular process.

153. Based upon Relator's personal knowledge and experience, Defendant Upsher-Smith Lab often disciplines or otherwise retaliates against its employees who take time to properly document and complete a cleaning process. This system results in the commonplace falsification of the Confirmation Slips so that the actual production time is often internally underreported. While Confirmation Slips are not a cGMP-required type of documentation, they reflect Defendant's obsession with "production, production, production," in the words of Quality Associate Stephanie Gibson, at the expense of care and compliance.

154. Employees, including Relator, who accurately complete and record major and minor cleans, both on Confirmation Slips and on the cGMP-required documentation described in further detail below, are subject to harassment and discipline.

155. For example, throughout Relator's career at Defendant, from 2011 until September 2018, pursuant to Defendant's written protocol but against management's actual policy, Relator would report, or in the words of Quality Associate Stephanie Gibson, "escalate," cGMP concerns to Shift Leads Joseph Leuer, Todd Lange and Solomon Tewolde.

156. In response, these three Shift Leads, or supervisors, would question the need for the escalation, which often requires a shutdown of the manufacturing line at issue and accordingly a decrease in the production rate, and accordingly demand that Relator

falsify the related clean documentation and withhold "escalation." Subsequently, Relator's attempts to "escalate" quality issues would be referenced in his down-graded performance reviews as Relator having a "poor attitude."

157. Indeed, in Relator's 2012 review that otherwise cited Relator's various positive qualities, Operations Supervisor Gary Parker noted his concern that Relator could occasionally "become overly engrossed in the nuances or "gray areas" of certain equipment or process related issues," referencing Relator slowing down the rapid-fire production operation in order to assure cGMP compliance by properly documenting failures," and "escalating" problems to management.

158. The retaliatory environment also impacted other Operators. For example, Relator's former co-worker, Victor Rodriguez, reported an internal audit "failure" in a potassium chloride tablet batch to Shift Lead Joe Leuer on May 4, 2018. He was verbally reprimanded by Leuer, who then, in consultation with Second-Shift Lead Solomon Tewolde, ordered another Operator to "re-do" the audit and falsely omit the "failure" from the related documentation.

159. On several occasions Relator complained about the retaliatory environment to Defendant's Human Resources Manager Catherine Metzger. Metzger rebuffed his complaints and accused him of mischaracterizing the nature of the operations. She also refused Relator's requests to see the problems for herself or to involve Quality Assurance personnel.

160. On or about September 6, 2018, Relator received a formal Verbal Warning from Shift Supervisor Gary Parker, because Relator refused to falsely certify the completion of a cleaning checklist. Specifically, Relator was knowingly assigned by Parker to perform a two-person job by himself, and was then disciplined for leaving his "Check" section of the documentation blank.

VII. DEFENDANT'S FRAUDULENT CONDUCT

A. Defendant's Schemes Resulting in Dangerous cGMP Violations and False Documentation of Such Violations

161. Within Relator's first two weeks of employment at Defendant Upsher-Smith Labs, he experienced his first cGMP violation and, perhaps more importantly, he also learned firsthand that Defendant Upsher-Smith Lab's supervision and management's focus was not cGMP compliance itself. Relator learned instead that Defendant Upsher-Smith Labs' focus was actually to provide only the *appearance* of cGMP compliance by falsifying documentation, making it possible to reduce production costs by avoiding *actual* compliance with FDA drug manufacturing requirements and continuing to pump out the potentially or actually adulterated drugs into the market.

162. Specifically, while performing his duties as an Upsher-Smith Labs Packager in mid-2011, Relator was randomly selecting bottles of pills and twisting their tops counter- clockwise to check for tightness. When he came across a loose top, he informed his supervisor so that the "failure" could be documented as required by the cGMPs. The supervisor, Gary Parker, nonchalantly instructed Relator to "*put it back and pick another.*"

163. In the instances described in the above paragraph, per supervisory directive no "failure" was documented. Relator thus learned early in his tenure with Defendant, as did all of his co-workers, that employees failed when they documented "failures."

164. The routine and matter-of-fact falsification of the referenced required "random" selection illustrates Defendant Upsher-Smith Labs' culture of chronic quality assurance problems and ongoing, serious cGMP violations which go to the heart of Defendant's manufacturing, processing, and packaging systems.

165. As further detailed below, Defendant Upsher-Smith Labs' routine cGMP violations included and/or resulted in:

a. Inadequate or non-existent process validation and failure to execute supporting validation documentation, including unsigned, undated, and falsified validation documents, including Cleaning Checklists and Logbooks;

b. Inadequate or non-existent calibration of equipment and instruments, inadequate calibration monitoring, and incomplete investigations and of equipment found to be out-of-calibration;

c. Understaffing of the quality assurance department, which Defendant knows makes cGMP compliance frequently impossible;

d. Contamination of products manufactured in a purportedly clean facility;

e. Manufacturing areas and equipment that repeatedly failed routine visual inspection of cleanliness and exhibited gross residual product;

f. Falsification of internal audit reports after discussion with the responsible personnel, contrary to and with willful disregard or ignorance of Defendant Upsher-Smith Lab's own policy and industry practice requiring 3-year retention; and

g. Substandard equipment storage facilities not meeting cGMP standards and creating the potential for cross-contamination.

166. The above-summarized chronic and serious deficiencies in the quality assurance function at Defendant's plants, including its Plymouth, Minnesota facility, result in false claims. Specifically, the Government only agrees to pay for non-adulterated drugs for its healthcare Beneficiaries. Yet, as a result of the schemes of deficiencies and corresponding cGMP violations in Defendant's drug operation, the Government was bilked out of Taxpayer's funds when it unwittingly paid for the false assurance of drug quality and fitness-for-use for all claims submitted to the Government for products manufactured by Defendant Upsher-Smith Labs during the time period relevant to this complaint.

167. Defendant knew, given the nature of its products and the identity of its customers and end-users, that widespread payment by the Government for Defendant's products through Medicare, Medicaid and other similar programs was inevitable and, in fact, occurring.

168. To hide its knowing role in the submission of false claims, Defendant Upsher-Smith Labs falsified documentation to show that Defendant had followed the cGMP requirements when, in fact, it had not.

169. Defendant Upsher-Smith Labs also implemented practices and procedures designed to, and which do in fact, deceive FDA inspectors who visit Defendant Upsher-Smith Labs' facilities by, as described below, *inter alia*, (1) delaying inspectors; (2) physically hiding non-compliant equipment and documentation; and (3) threatening and instructing employees not to answer questions or otherwise provide complete information to inspectors even upon request.

1. Defendant's Culture of Noncompliance, Fraud, and Fear of Retaliation

170. Defendant Upsher-Smith Labs' cGMP violations can be organized roughly into two overlapping categories: (1) failure to implement cGMP-required cleaning and maintenance processes and procedures; and (2) falsification of the *documentation* required to substantiate implementation and compliance of these and other cGMP-required processes and procedures.

171. These two schemes are facilitated in large part by a pervasive culture of fraud and non-compliance driven by a distorted view of what it means to be "efficient." In other words, Defendant drives efficiency by simply forgoing those aspects of cGMP compliance it finds overly burdensome and time consuming, namely, cleaning and documentation.

172. The two types of cGMP-required documentation most commonly falsified by Defendant Upsher-Smith Labs are thus: (1) equipment logbooks, which verify the completion of cleaning procedures critical to patient safety and (2) cleaning checklists, which verify that such procedures were done *correctly*. The completion of these procedures and documentation takes time and sufficiently trained personnel.

173. A cleaning checklist is required for each of Defendant's machines and contains a step-by-step breakdown of how and what to clean. As described above with regard to logbook completion, completion of most checklists, particularly those pertaining to a "major" clean as described below, requires two people: one to complete the physical cleaning and another to *verify* the cleaning was completed and performed in compliance with the checklist.

174. Thus, Defendant management's refusal to hire and staff sufficiently creates a vicious cycle that includes a lack of proper supervision and lack of the required "double-check" clean verification process described above, as employees are expected to wander around the facility searching for an employee from another area *after* a clean is purportedly finished to come and fraudulently sign to attest that he or she witnessed and verified the cleaning operation when in fact, they did not.

175. Relator observed this fraudulent process, described in the above paragraph, on a nearly *daily* basis.

176. Generally, a "major" clean is more thorough, takes more time, and is required when a piece of equipment is about to be used to make *a different drug*, in which

case the risk of contamination posed by the existence of residual chemical ingredients in the equipment is high.

177. "Minor" cleans, in contrast, while still important to maintaining consistent drug purity and dosage strength, are less thorough. They are required between batches *of the same drug*.

178. Defendant's purported quality assurance systems are inadequate to establish that its major and minor clean procedures are being followed and that cleans are actually being performed at all.

179. For example, Defendant's "Integrated Quality Management team" consists of Quality Associate employees who constitute the entirety of Defendant Upsher-Smith Lab's quality assurance apparatus or "internal auditors." This "Integrated Quality Management team," is grossly understaffed, grossly undertrained, and serves a purely ceremonial purpose.

180. Based upon Relator's personal knowledge and experience, the Quality Associates do no more than merely glance at the verification forms. They do not actually confirm whether the equipment is in a clean state.

181. For example, when Relator informed Quality Associate Stephanie Gibson via text message of the above-referenced falsification incident involving Victor Rodriguez, Gibson candidly acknowledged, "*It's not surprising. I'm sure shit like this happens all the time...There's no proof and no honesty.*"

182. Similarly, on April 26, 2018, Relator informed Gibson of a cGMP violation involving Defendant's ordering that certain walls be chipped, scraped, and painted in the Manufacturing Department while drug product was being formulated nearby and below. Gibson simply replied, "*Nice. Don't stop production for quality....Obviously nobody cares...That's what sucks about being in [the QA Department]. You know sketchy shit happens but everyone above you covers it up.*"

183. But even if Defendant had its Quality Associate employees do more than simply go through the motions, Defendants would have continued to evade compliance. By Defendant's design, the Quality Associate employees have very little knowledge of the manufacturing process and are not provided training on what actually constitutes a necessary and sufficient "clean" for a particular piece of equipment.

184. Thus, Defendant's Quality Associate employees merely document their meaningless review of records they know may be falsified.

185. At the same time, those of Defendant's employees who *do* understand the manufacturing process and the equipment, namely the Formulators and Operators, receive no training on compliance beyond a meaningless acknowledgment at hire of the existence of a Standard Operating Procedure for cleanings.

186. Defendant does not confirm that any of its employees actually read the Standard Operating Procedures and Defendant provides no follow-up on the SOPs or any training about proper cleaning procedures or requirements.

187. Thus, by intentionally keeping its manufacturing and quality assurance employees ignorant of the "details" of the others' job duties and process, Defendant insulates its schemes from both internal and external scrutiny.

188. On several occasions in 2015 and 2016, Relator was expressly directed by Shift Supervisor Gary Parker to "*make things up as [you] go*" upon inquiring about a particular cleaning procedure.

189. Relator's knowledge regarding the above-described staffing and training deficiencies and Defendant's knowledge thereof stems from, *inter alia,* his experiences in monthly Operations Meetings for the Department of Operations at the Defendant's Plymouth, Minnesota plant.

190. Defendant's monthly Operations Meetings included Formulators, Operators, Packagers and management including Shift Leads Joe Leuer, Todd Lange, and Solomon as well as Associate Director of Manufacturing Operations Amy Niesen and other Directors from Quality Assurance and Human Resources. At the meetings, Relator and other employees often would verbally raise concerns regarding cGMP compliance, staffing, and training. Each time, their concerns would, at best, receive lip-service if not hostility from Management, including former Operations Supervisors William Thompson and Gary Parker and Associate Director of Manufacturing Operations Amy Niesen. No actual changes were made.

191. Defendant also retaliated against Relator for attempting to stop false claims as part of his participation in the above-described Operations Meetings.

192. For example, in early 2016 and late 2016 Defendant denied Relator promotions to positions for which he had applied and for which he was qualified. During Relator's interviews for the promotions, his former supervisor, Dan Engle, informed Relator that they were just going through the motions by interviewing him and that he was not actually being considered for the position.

193. In late 2016, Supervisor Engle told Relator that Defendant Upsher-Smith Labs would not consider Relator for the promotion because management did not "like" him since he was a "troublemaker" and "whistleblower." Relator's former supervisor Brandon Waite corroborated this for Relator, both before and after Relator's interview with Engle.

2. Specific Examples of Defendant's cGMP Violations

194. This retaliatory environment combined with understaffing, lack of training, and comparatively low pay results in an environment that sees every employee being used by Defendant Upsher-Smith Labs as part of a scheme to defraud not only the FDA but also Medicare Part D sponsors and all other downstream entities who purchase or in some way fund the purchase of Defendant Upsher-Smith Labs' prescription medications.

195. Specific examples of Defendant Upsher-Smith Labs' systematic cGMP violations and corresponding documentation of falsification include the following examples, wherein Relator personally observed and photographed the relevant machinery and falsified documentation:

a. On August 12, 2016, Operator Terry Slather validated in the Use and Clean Logbook for a tablet drum dumper which transports a "drum" full of drug tablets onto a tray to be coated, stating that Operator Daniel Brebeck had completed a "minor clean" of the dumper following its use on a batch of potassium chloride tablets. Although, the dumper was left coated with gross residual product indicating that a minor clean had not been completed, Operator Terry Slather falsely signed the Clean Logbook because he was told to so by Defendant supervisor Greg Parker.

b. On November 16, 2016, Operator Greg Effering validated in the Use and Clean Logbook for Auger No. 10649 that Operator Clint Stewart had completed a "minor clean" of the auger following its use on a batch of cholestyramine, a blood pressure medication. In fact, the auger was left contaminated with chunks of chemical particulate, and Stewart falsely signed the Clean Logbook at the direction of Defendant supervisor Greg Parker. Moreover, the logbook indicates that a Quality Associate, "Nou V," also falsely claimed to have validated the clean as part of an audit.

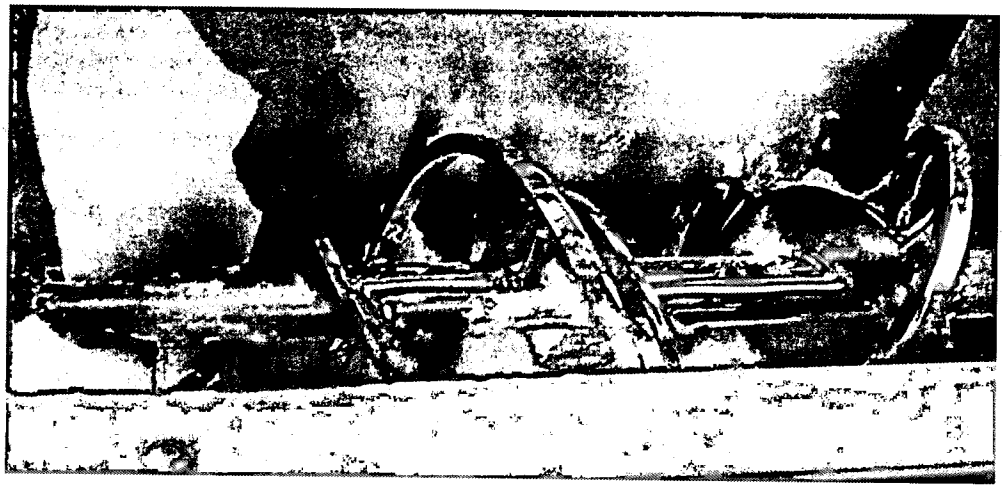
c. On January 25, 2017, Operator Clint Stewart validated in the Use and Clean Logbook for Auger No. 10649 that Operator Greg Effering had completed a "major clean" of the auger following its

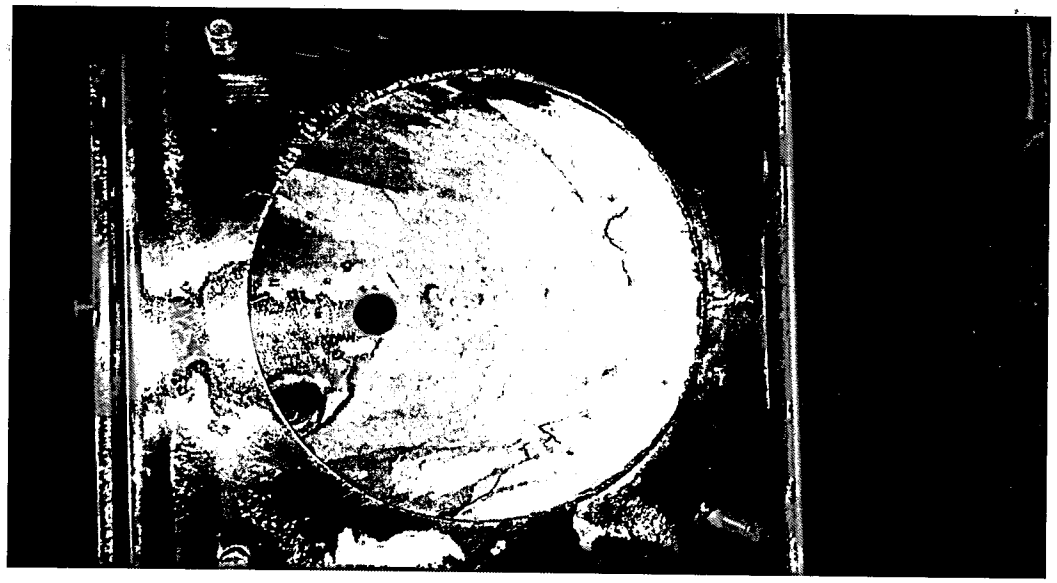
use on a batch of Divolproah Potassium. In fact, the auger was left contaminated with chunks of chemical particulate, and Stewart falsely signed the Clean Logbook at the direction of Defendant supervisor Bill Thompson or Greg Parker.

d. On February 3, 2017, one of Defendant's Operators validated in the Use and Clean Logbook for Auger No. 10649 that another Operator had completed a "major clean" of the auger following its use on a batch of cholestyramine. In fact, the auger was left contaminated with chunks of chemical particulate, and the Operator falsely signed the Clean Logbook at the direction of Defendant supervisor Thompson or Parker.

e. On April 6, 2017, Defendant's fluid bed processes were contaminated with metal, resulting in the need for an unscheduled "major clean" of several prices of equipment. However, several pieces of equipment which had been contaminated, including a vacuum conveyor, were omitted and not cleaned at all. The next day, April 7, 2017, Shift Lead Solomon Tewolde ordered Relator to falsify the Logbook to indicate that the equipment had been cleaned, instructing Relator, over Relator's objections, where and what to write.

196. The auger referenced in the above examples was never cleaned, and in fact was caked in chemical particulate as demonstrated by these contemporaneous photographs, respectively taken by Relator in February 2017 and June 2017 to document the dangerous violation:





197. The photographs above represent the condition of multiple machines at any given time or day over the past seven years at Defendant's Plymouth, Minnesota plant, where cleans are frequently incomplete or not completed at all.

198. As a result of the above-described pressure on their time, Shift Supervisors and Shift Leads have downplayed the importance of cleans and consistently engaged in willful ignorance when a clean is skipped, while expressly directing the responsible Operators and Formulators to create falsified Log Book entries and other documentation associated in an effort to manufacture product faster. Supervisory directives are to provide the appearance, but not the fact of cGMP compliance.

199. For example, as illustrated further below, Shift Leads and Shift Supervisors would routinely respond to concerns raised by Relator and others about visibly or potentially contaminated drug product or other process deviations with statement such as, "*It doesn't matter,*" "*don't worry about it*" and "*it won't affect the product.*"

200. Even when a good faith effort to complete a cleaning or maintenance process is undertaken, Confirmation Slips will document that a process intended to take two employees 6 personnel hours each was somehow performed by just one employee in about that same time.

B. Defendant's Scheme Results in Potentially Contaminated Drugs

201. While the widespread nature of above-described scheme can make it difficult to identify and separate more serious violations, such as those in which the failure-to-clean scheme and related non-compliance actually results in contaminated end product, Relator has identified instances in which, as a result of the systemic non-compliance, potentially harmful chemical particulate came into direct contact with

potassium chloride tablets and cholestyramine, two of Defendant Upsher-Smith Labs' biggest selling prescription drugs,.

202. Critical to these and similar contaminations is the fact, as required by Defendant Upsher-Smith Labs' management as a condition of employment, that falsification is a regular daily occurrence at Defendant Upsher-Smith Labs' facilities, including Defendant's Plymouth, Minnesota plant.

203. For example, following an "exception type event," such as an equipment malfunction that could have resulted in the introduction of contaminant to the product, the Lead employees will direct Operators to leave documents incomplete for days or more while a convincing and suitable "story" is developed to ensure that there is no product loss.

204. Following the investigation where the storyline is developed, a Shift Lead will walk the lower level employee through the steps to complete the documentation so that the corresponding story is corroborated by the associated documentation to show that the cleans were performed, when in fact they were not performed. Relator observed this process unfold on at least a weekly basis.

205. For example, Shift Lead Gary Parker on several occasions would respond to a report of a deviation—such as suspected foreign materials in product—by instructing the Operators and Formulators who discovered it, "don't worry about it," only to "escalate" the matter weeks later. The escalation was then accompanied by a bogus technical explanation for why the deviation(s) applied only to a certain limited set of

batches, blaming the deviation on a temporary, already-solved problem with the machine or equipment, when in fact he had made no attempt to verify or address the actual cause.

206. Likewise, following instances of potential contamination where a contaminate is found in the product stream, Defendant's FDA-approved SOP indicates that Operators are to escalate and involve Lead personnel who are to involve Quality and Technical Services to initiate an investigation and to document findings to identify of the contaminate and the drug products potentially impacted.

207. Instead, Lead employees direct Operators **not** to document that the "line went down," meaning that the manufacturing process was interrupted due to some malfunction or other process failure, including the discovery of contaminate. Thus, Operators are directed not to document the discovery contaminate. If the deviation is reported to a Quality Assurance Associate, similar directives to falsify are given to them, so there is no "traceability" to any instance of potential contamination.

208. Defendant's procedure, as summarized by Shift Supervisor Gary Parker, is to "make it as if it never happened," referring to potential exception type events.

1. Defendants' Contaminated Potassium Chloride

209. A specific example of such an "exception type event" is the case of Defendant Upsher-Smith Labs' American Blender, used to mix hydrogenated vegetable oil and other inert substances to create "filler" for subsequent addition to a batch of potassium chloride tablets.

210. Beginning by at least mid-2016, the American Blender began to malfunction. A heating element in contact with a Teflon plastic bushing became so hot that the bushing liquefied, causing melted Teflon plastic to drip into the filler pre-mix in significant quantities.

211. The candlewax-like dripping on the underside of the circular, yellowish bushing component below illustrates the residue and effect of the above-described heating and melting:

212. The toxicity of melted plastic is widely recognized and depends on the type of plastic and its precise chemical makeup. For example, polystyrene, polypropylene, polyvinyl and other "polycarbonate" chemicals commonly used in plastics such as Teflon have been linked to various types of cancers and other negative health effects despite being considered safe when properly used. Gifford, *20 Ways to Give Up Plastics and the Toxins In It*, Small Footprint Family, [accessed Nov. 4, 2018], https://www.smallfootprintfamily.com/avoiding-toxins-in-plastic (collecting studies).

213. Defendant Upsher-Smith Labs is well aware of the American Blender's overheating and resulting introduction of melted plastic and Teflon bushing material into the compounded drugs, as well as the fact that regardless of its toxicity, the malfunction constitutes an "exception event."

214. Indeed, on or about October 20, 2016, Relator detected dark specks inside raw, uncoated tablets of potassium chloride:

215. When Relator brought the visibly contaminated tablets to the attention of Shift Supervisor Gary Parker, Parker replied, "*They're tablets. Coat them. Nobody is going to see that. It'll be fine.*" Accordingly, the tablets were coated and no investigation was initiated despite the risk that thousands of tablets containing Teflon plastic and/or some other unidentified foreign substance were subsequently released to the public. Finally, several weeks later, an Exception Report was issued whereby Parker, in consultation with Shift Leads, devised a false narrative for Quality Associates to rely on. The narrative falsely claimed that only a limited number of identified batches were impacted, when in reality no investigation was conducted and there was no knowledge about how many batches were contaminated.

216. Parker's above detailed conduct in reaction to the detection of contaminated tablets is routine at Defendant Upsher-Smith Lab, where the push for production results in Shift Leads and Supervisors failing to timely investigate and stop production to ensure the drugs are not contaminated or adulterated in order to maintain the highest possible production levels and reduce any documentation of potential contamination.

217. Indeed, the likely role in contamination played by the dripping of melted bushing into the filler mix was never fully addressed. The problem and corresponding risk of contamination continued, on and off, for at least nearly another two years.

218. For example, on August 22, 2018, Shift Lead John Leuer emailed Shift Supervisor Bill Thompson and Operations Director Amy Niesen a copy of the above photograph of contaminated tablets, as well as other similar photos of the melted bushing,

stating, "Operators came to me about twenty minutes ago with concerns about the American blender spray bar melting *again*. I have attached a few pictures, *looks similar to the last time this happened June 8, [2018]*. Maintenance has been notified, operators were told not to scrape the blender…" [Emphasis added.]

219. An "exception event" requires that the production process cease so the machine can be evaluated. Such a suspension would then be documented as a "deviation" in the final record of each exposed batch. However, ceasing production also reduces production and thereby reduces profit.

220. For at least two years, Defendant Upsher-Smith Labs' practice, as illustrated by Leuer's email, has been to simply wait for the quarterly "major clean" of the American Blender and only then replace the melted bushing seemingly in the normal maintenance schedule, rather than fix or replace the machine and/or the malfunctioning heating element as part of an exception event. No deviation was documented.

221. As a result, there is an unknown but inevitable period of time prior and subsequent to each "major clean" of the American Blender during which the melted bushing drips Teflon plastic into the drug product resulting in thousands of potentially contaminated tablets like those pictured above.

222. As described above, Defendant's actual practice with regard to the melted Teflon plastic is to direct Operators not to document the "deviation" and, instead, to keep the production rolling out the adulterated drugs that will eventually be consumed by

Government Beneficiaries and be billed to and unwitting paid for by the Government which prohibits payment for adulterated drugs.

223. The motive for this falsification by failing to document deviations is even stronger and more apparent and direct than the Defendant's desire to avoid FDA scrutiny that generally motivates the falsification of Cleaning Checklists and Logbooks: rapidly produce the drugs without delay and with as few personnel as possible; then sell the drugs and get paid.

224. The motive is this: Sandoz, a pharmaceutical company and the largest single purchaser of Defendant Upsher-Smith Lab's potassium chloride tablets, maintains a policy of purchasing only drug batches from Defendant Upsher-Smith Labs that have been manufactured without any deviation.

225. Thus, any documented admission or record of the deviation caused by the defective American Blender and melted bushing could result not only in the rejection by Sandoz of lucrative batches of potassium chloride tablets but also, given the longstanding nature of the problem and the corresponding deception, the rejection by Sandoz of its business relationship with Defendant Upsher-Smith Labs entirely.

2. Defendant's Potentially Contaminated Cholestyramine

226. This second, similar specific example of cGMP violations resulting in an identifiable risk of contamination involves neither a failed cleaning nor an undocumented exception event, rather a failure to store critical equipment in a properly sterile environment.

227. Specifically, an array of equipment, including a large auger and auger-feeder tube apparatus used to manufacture cholestyramine, a common cholesterol medication, require a special type of "major clean" that involves the use of a vacuum-like, special pump device.

228. The pump is used to ensure that *excess moisture* from one batch is not absorbed by the next which could degrade the drug. When Defendant Upsher-Smith Labs does not skip this step entirely, which it often does, Defendant uses a dirty pump that is stored wherever it fits at the time, despite documentation certifying that the pump was cleaned and stored in a special, sterile room.

229. In addition to the pump, other "in-process equipment" critical to the cholestyramine manufacturing process is stored and cleaned in immediate proximity to other equipment caked with active and inactive ingredients from other drugs.

230. During the "cleaning" process, which typically involves the use of fans and pressure washers, the particulate on adjacent equipment can easily be transferred to equipment stored in the same area, causing a gross contamination of the processing equipment.

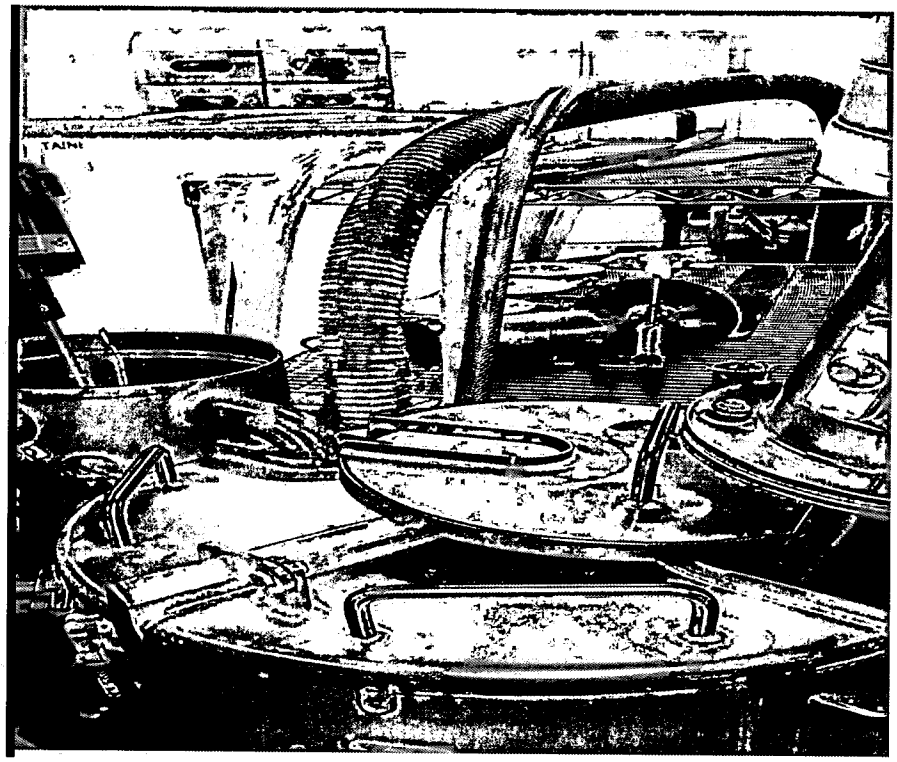
231. Indeed, the risk of such cross-contamination is precisely why Defendant Upsher-Smith Labs has FDA-mandated and approved policies on paper requiring that certain equipment be stored and cleaned in certain designated sterile rooms.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

232. But Defendant's Operators and Formulators are routinely allowed and directed to ignore these policies by storing and cleaning equipment wherever is most convenient, in order to save time and "turn over" more product.

233. The contaminated storage of dirty cleaning equipment and dirty manufacturing equipment in Formulation rooms (where drugs are made) and other unsanitary rooms has been Defendant's routine practice with regard to cholestyramine and other drugs since at least 2013. The following photographed examples are from December 19, 2016, January 31, 2017 and March 15, 2017, respectively:

a.



Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

b.

c.

234. Each of the above photographs includes stainless steel and plastic equipment such as containers, tanks, vats, pipes, tubing and other materials used in direct contact with drug components and drug products during the manufacturing process of drugs including cholestyramine. Thus, each piece of equipment must be stored and cleaned in a cGMP-compliance "clean room." As its name suggests, a clean room is one containing only equipment that has been subject to a verified, completed clean.

235. But as the above photographs make clear, Defendant Upsher Smith Labs simply stores its equipment wherever it fits, oftentimes alongside equipment caked with and/or otherwise surrounded by residual product.

236. Moreover, the above examples are three of dozens of similar violations occurring at any given time on any given day at Defendant Upsher-Smith Labs facilities, including Defendant's Plymouth, Minnesota facility, where cGMP-covered equipment is sometimes stashed in open hallways or near ongoing construction or other maintenance.

237. As described below, the only time that this situation changes at all is when Defendant has reason to believe that an audit or FDA inspection is in the offing.

C. Defendants' Scheme to Defraud FDA Inspectors

238. After the 2010 recall detailed above, Defendant Upsher-Smith Labs adopted a two-pronged approach to preventing future product recalls. This approach included both a proactive and a reactive component, but both were intended to thwart cGMP compliance.

239. In what is best described as the fostering an "us versus them" culture with regard to the FDA, beginning immediately after the investigations that accompanied and followed the FDA-triggered recall, Defendant Upsher-Smith Labs focused its efforts on training its employees, from upper management down to Operators, Formulators, and Packagers, how to thwart the effectiveness of any inspection, whether by FDA inspectors or auditors from the state or potential or existing wholesale customers.

240. First, Defendant's Training Staff, including Training Associate Matthew Lindgren, with and through Shift Supervisors such as Bill Thompson and Gary Parker, train employees on specifically how to lie to inspectors.

241. For example, supervisors instruct Operators like Relator to withhold from inspectors "any information that may be used against the company." Specifically, Operators are trained to obfuscate when asked questions about cGMP or operations generally by asking inspectors to "*rephrase their questions*" and to repeatedly tell inspectors who ask difficult questions that they "*don't understand the question*" or to repeatedly ask for "*clarification*" or "*a more specific question*" until the inspector moves on.

242. In other words, Defendant Upsher-Smith Labs expressly instructs and trains its staff to play dumb when interacting with inspectors.

243. As with cGMP violations, Defendant Upsher-Smith Labs' management secures its staff's complicity through threats. Specifically, management tells employees that cooperation with inspectors may lead to them being held personally responsible for any wrongdoing or noncompliance uncovered by inspectors, particularly because the Operators have previously signed their name to false documentation.

244. For example, one type of threat that harkens back to the days immediately following the 2010 recall has been repeated so often by management that it has become something of a running joke among some of Defendant Upsher-Smith Labs' Operators: according to Shift Supervisors like Gary Parker or Director of Quality Management

Charles Bornhoeft, employees who cooperate with inspectors or auditors will be subject to intense and intimidating questioning by mysterious "corporate attorneys" and subject to the chance that "*the FDA can come to your house and pull you off the couch in the middle of the Super Bowl and question you about whatever you tell them, so don't talk to them.*"

245. Second, in addition to proactively conditioning its employees to fear inspectors and training them to resist their questions, Defendant Upsher-Smith Labs also has specific policies and procedures governing how employees are to react to notice of an impending audit or inspection.

246. This trained response to an impending inspection is designed to take place at a moment's notice.

247. Given that even the most random of audits includes at least several hours' notice to company management, the reaction begins when managers at the Maple Grove, Minnesota corporate office, where inspectors first arrive, relay the notice of the audit or inspection to Operations Director Amy Niesen and her Shift Supervisors at the Plymouth, Minnesota plant approximately a 10-minute drive away.

248. As soon as the Supervisors and Leads receive word, they spring into action, coordinating with each other to direct staff to rapidly hide the myriad cGMP violations described above by physically collecting dirty or defective equipment, unapproved tools and equipment, unapproved policies and written falsification directives, and obsolete or

incorrect training materials and hiding it in offices or backrooms to avoid arousing an inspector's suspicion.

249. As Relator put it in a June 20, 2018 text message to Quality Associate Stephanie Gibson, word of an impending inspection sends Supervisors and Leads "scurrying around like ants" to which Gibson replied, "Yup. Per usual."

250. Relator experienced this audit alert routine designed to thwart the FDA on June 20-21, 2018 during an FDA inspection conducted at Defendant's Plymouth, Minnesota plant. According to Director of Quality Management Chuck Bornhoeft in a meeting held about a month prior in which he warned that Defendant was "overdue" for an FDA inspection, the July 20-21 inspection was the first on-site inspection of the plant in at least four years.

251. On or about June 20, 2018, Relator directly observed Training Associate Matthew Lindgren spring into action by rapidly filling a grey plastic storage bins with the above-described contraband and running across the Manufacturing Department to his office to hide it.

252. On information and belief, Defendant' scheme worked, and the FDA issued no Form 483 identifying any objectionable conditions. Within days of the completion of the inspection, however, Defendant resumed its open, constant, systematic violation of core cGMP requirements intended to safeguard patients, including Beneficiaries of Government healthcare programs.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

VIII. COUNTS

COUNT ONE

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT 31 U.S.C. § 3729(a)(1)(A)

False Claims for Adulterated Drugs

253. Relator realleges and incorporates by reference the allegations of all previous paragraphs as if restated herein.

254. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

255. 31 U.S.C. § 3729(a)(1)(A) states that "any person who . . . knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval" is liable under the Act.

256. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of 31 U.S.C. § 3729(a)(1)(A).

257. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

258. By reason of Defendant's acts and omissions, the United States has suffered substantial actual damages.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

COUNT TWO

VIOLATIONS OF THE ALASKA FALSE CLAIMS ACT AS 09.58.010 *et seq.*

False Claims for Adulterated Drugs

259. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

260. This is a claim for treble damages and civil penalties under the Alaska False Claims Act, AS 09.58.010 *et seq.*

261. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Alaska False Claims Act, AS 09.58.010 *et seq.*

262. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

263. By reason of Defendant's acts and omissions, Alaska has suffered substantial actual damages.

COUNT THREE

VIOLATIONS OF THE ARKANSAS FALSE CLAIMS ACT Ark. Code Ann. §20-77-901

False Claims for Adulterated Drugs

264. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

265. This is a claim for treble damages and civil penalties under the Arkansas False Claims Act, Ark. Code Ann. §20-77-901.

266. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Arkansas False Claims Act, Ark. Code Ann. §20-77-901.

267. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

268. By reason of Defendant's acts and omissions, Arkansas has suffered substantial actual damages.

COUNT FOUR

VIOLATIONS OF THE CALIFORNIA FALSE CLAIMS ACT
Cal. Gov't Code §12651 *et seq.*

False Claims for Adulterated Drugs

269. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

270. This is a claim for treble damages and civil penalties under the California False Claims Act, Cal. Gov't Code §12651 *et seq.*

271. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the California False Claims Act, Cal. Gov't Code §12651 *et seq.*

272. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

273. By reason of Defendant's acts and omissions, California has suffered substantial actual damages.

COUNT FIVE

VIOLATIONS OF THE COLORADO FALSE CLAIMS ACT §25.5-4-303.5 *et seq.*

False Claims for Adulterated Drugs

274. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

275. This is a claim for treble damages and civil penalties under the Colorado False Claims Act, Colo. Rev. Stat. §25.5-4-303.5 *et seq.*

276. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Colorado False Claims Act, Colo. Rev. Stat. §25.5-4-303.5 *et seq.*

277. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

278. By reason of Defendant's acts and omissions, Colorado has suffered substantial actual damages.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

COUNT SIX

VIOLATIONS OF THE CONNECTICUT FALSE CLAIMS ACT
Conn. Gen. Stat. §176-301a *et seq.*

False Claims for Adulterated Drugs

279. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

280. This is a claim for treble damages and civil penalties under the Connecticut False Claims Act, Conn. Gen. Stat. §176-301a *et seq*.

281. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Connecticut False Claims Act, Conn. Gen. Stat. §176-301a *et seq*.

282. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

283. By reason of Defendant's acts and omissions, Connecticut has suffered substantial actual damages.

COUNT SEVEN

VIOLATIONS OF THE DELAWARE FALSE CLAIMS ACT
Del. Code Ann. tit. 6, §1201 *et seq.*

False Claims for Adulterated Drugs

284. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

285. This is a claim for treble damages and civil penalties under the Delaware False Claims Act, Del. Code Ann. tit. 6, §1201 *et seq*.

286. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Delaware False Claims Act, Del. Code Ann. tit. 6, §1201 *et seq*.

287. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

288. By reason of Defendant's acts and omissions, Delaware has suffered substantial actual damages.

COUNT EIGHT

VIOLATIONS OF THE DISTRICT OF COLUMBIA FALSE CLAIMS ACT D.C. Code §2-308.14 *et seq.*

False Claims for Adulterated Drugs

289. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

290. This is a claim for treble damages and civil penalties under the District of Columbia False Claims Act, D.C. Code §2-308.14 *et seq*.

291. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the District of Columbia False Claims Act, D.C. Code §2-308.14 *et seq*.

292. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

293. By reason of Defendant's acts and omissions, the District of Columbia has suffered substantial actual damages.

COUNT NINE

VIOLATIONS OF THE FLORIDA FALSE CLAIMS ACT
Fla. Stat. Ann. §68.081 *et seq.*

False Claims for Adulterated Drugs

294. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

295. This is a claim for treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. Ann. §68.081 *et seq*.

296. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Florida False Claims Act, Fla. Stat. Ann. §68.081 *et seq*.

297. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

298. By reason of Defendant's acts and omissions, Florida has suffered substantial actual damages.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

COUNT TEN

VIOLATIONS OF THE GEORGIA FALSE CLAIMS ACT
GA. Code Ann. §49-4-168 *et seq.*

False Claims for Adulterated Drugs

299. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

300. This is a claim for treble damages and civil penalties under the Georgia False Claims Act, GA. Code Ann. §49-4-168 *et seq.*

301. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Georgia False Claims Act, GA. Code Ann. §49-4-168 *et seq.*

302. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

303. By reason of Defendant's acts and omissions, Georgia has suffered substantial actual damages.

COUNT ELEVEN

VIOLATIONS OF THE HAWAII FALSE CLAIMS ACT
Haw. Rev. Stat. §661-22 *et seq.*

False Claims for Adulterated Drugs

304. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

305. This is a claim for treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. §661-22 *et seq.*

306. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Hawaii False Claims Act, Haw. Rev. Stat. §661-22 *et seq.*

307. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

308. By reason of Defendant's acts and omissions, Hawaii has suffered substantial actual damages.

COUNT TWELVE

VIOLATIONS OF THE ILLINOIS FALSE CLAIMS ACT 740 Ill. Comp. Stat. 175/1 *et seq.*

False Claims for Adulterated Drugs

309. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

310. This is a claim for treble damages and civil penalties under the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq.*

311. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Illinois False Claims Act, 740 Ill. Comp. Stat. 175/1 *et seq.*

312. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

313. By reason of Defendant's acts and omissions, Illinois has suffered substantial actual damages.

COUNT THIRTEEN

VIOLATIONS OF THE INDIANA FALSE CLAIMS ACT Indiana Code §5-11-5.5

False Claims for Adulterated Drugs

314. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

315. This is a claim for treble damages and civil penalties under the Indiana False Claims Act, Indiana Code §5-11-5.5.

316. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Indiana False Claims Act, Indiana Code §5-11-5.5.

317. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

318. By reason of Defendant's acts and omissions, Indiana has suffered substantial actual damages.

COUNT FOURTEEN

VIOLATIONS OF THE IOWA FALSE CLAIMS ACT
Iowa Code §685.1 *et seq.*

False Claims for Adulterated Drugs

319. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

320. This is a claim for treble damages and civil penalties under the Iowa False Claims Act, Iowa Code §685.1 *et seq.*

321. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Iowa False Claims Act, Iowa Code §685.1 *et seq.*

322. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

323. By reason of Defendant's acts and omissions, Iowa has suffered substantial actual damages.

COUNT FIFTEEN

VIOLATIONS OF THE LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
La. Rev. Stat. §46:439.1 *et seq.*

False Claims for Adulterated Drugs

324. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

325. This is a claim for treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §46:439.1 *et seq.*

326. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §46:439.1 *et seq.*

327. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

328. By reason of Defendant's acts and omissions, Louisiana has suffered substantial actual damages.

COUNT SIXTEEN

VIOLATIONS OF THE MARYLAND FALSE CLAIMS ACT
Md. Code Ann. Health-Gen §2-601 *et seq.*

False Claims for Adulterated Drugs

329. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

330. This is a claim for treble damages and civil penalties under the Maryland False Claims Act, Md. Code Ann. Health-Gen §2-601 *et seq.*

331. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Maryland False Claims Act, Md. Code Ann. Health-Gen §2-601 *et seq.*

332. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

333. By reason of Defendant's acts and omissions, Maryland has suffered substantial actual damages.

COUNT SEVENTEEN

VIOLATIONS OF THE MASSACHUSETTS FALSE CLAIMS ACT Mass. Ann. Laws ch. 12, §5(A)-(O)

False Claims for Adulterated Drugs

334. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

335. This is a claim for treble damages and civil penalties under the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, §5(A)-(O).

336. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Massachusetts False Claims Act, Mass. Ann. Laws ch. 12, §5(A)-(O).

337. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

338. By reason of Defendant's acts and omissions, Massachusetts has suffered substantial actual damages.

COUNT EIGHTEEN

VIOLATIONS OF THE MICHIGAN FALSE CLAIMS ACT MCLA §400.601 *et seq.*

False Claims for Adulterated Drugs

339. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

340. This is a claim for treble damages and civil penalties under the Michigan False Claims Act, MCLA §400.601 *et seq*.

341. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Michigan False Claims Act, MCLA §400.601 *et seq*.

342. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

343. By reason of Defendant's acts and omissions, Michigan has suffered substantial actual damages.

COUNT NINETEEN

VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT 740 Minn. Stat. §§ 15C.01 *et seq.*

False Claims for Adulterated Drugs

344. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

345. This is a claim for treble damages and civil penalties under the Minnesota False Claims Act, 740 Minn. Stat. §§ 15C.01 *et seq.*

346. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Minnesota False Claims Act, 740 Minn. Stat. §§ 15C.01 *et seq.*

347. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

348. By reason of Defendant's acts and omissions, Minnesota has suffered substantial actual damages.

COUNT TWENTY

VIOLATIONS OF THE MONTANA FALSE CLAIMS ACT
Mont. Code Ann. §17-8-401 *et seq.*

False Claims for Adulterated Drugs

349. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

350. This is a claim for treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann. §17-8-401 *et seq.*

351. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Montana False Claims Act, Mont. Code Ann. §17-8-401 *et seq.*

352. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

353. By reason of Defendant's acts and omissions, Montana has suffered substantial actual damages.

COUNT TWENTY-ONE

VIOLATIONS OF THE NEVADA FALSE CLAIMS ACT
Nev. Rev. Stat. §357.010 *et seq.*

False Claims for Adulterated Drugs

354. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

355. This is a claim for treble damages and civil penalties under the Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq*.

356. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Nevada False Claims Act, Nev. Rev. Stat. §357.010 *et seq*.

357. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

358. By reason of Defendant's acts and omissions, Nevada has suffered substantial actual damages.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

COUNT TWENTY-TWO

VIOLATIONS OF THE NEW JERSEY FALSE CLAIMS ACT N.J. Rev. Stat. Ann. §2A:32c-1, *et seq.*

False Claims for Adulterated Drugs

359. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

360. This is a claim for treble damages and civil penalties under the New Jersey False Claims Act, N.J. Rev. Stat. Ann. §2A:32c-1, *et seq*.

361. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the New Jersey False Claims Act, N.J. Rev. Stat. Ann. §2A:32c-1, *et seq*.

362. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

363. By reason of Defendant's acts and omissions, New Jersey has suffered substantial actual damages.

COUNT TWENTY-THREE

VIOLATIONS OF THE NEW MEXICO FALSE CLAIMS ACT N.M. Stat. Ann. 1978, §27-14-1 *et seq.*

False Claims for Adulterated Drugs

364. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

365. This is a claim for treble damages and civil penalties under the New Mexico False Claims Act, N.M. Stat. Ann. 1978, §27-14-1 *et seq.*

366. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the New Mexico False Claims Act, N.M. Stat. Ann. 1978, §27-14-1 *et seq.*

367. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

368. By reason of Defendant's acts and omissions, New Mexico has suffered substantial actual damages.

COUNT TWENTY-FOUR

VIOLATIONS OF THE NEW YORK FALSE CLAIMS ACT N.Y. State Fin. Law §187 *et seq.*

False Claims for Adulterated Drugs

369. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

370. This is a claim for treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law §187 *et seq.*

371. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the New York False Claims Act, N.Y. State Fin. Law §187 *et seq.*

372. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

373. By reason of Defendant's acts and omissions, New York has suffered substantial actual damages.

COUNT TWENTY-FIVE

VIOLATIONS OF THE NORTH CAROLINA FALSE CLAIMS ACT N.C. Gen. Stat. §1-605, *et seq.*

False Claims for Adulterated Drugs

374. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

375. This is a claim for treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. §1-605, *et seq*.

376. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the North Carolina False Claims Act, N.C. Gen. Stat. §1-605, *et seq*.

377. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

378. By reason of Defendant's acts and omissions, North Carolina has suffered substantial actual damages.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

COUNT TWENTY-SIX

VIOLATIONS OF THE OKLAHOMA FALSE CLAIMS ACT Okla. Stat. tit. 63, §5053 *et seq.*

False Claims for Adulterated Drugs

379. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

380. This is a claim for treble damages and civil penalties under the Oklahoma False Claims Act, Okla. Stat. tit. 63, §5053 *et seq*.

381. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Oklahoma False Claims Act, Okla. Stat. tit. 63, §5053 *et seq*.

382. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

383. By reason of Defendant's acts and omissions, Oklahoma has suffered substantial actual damages.

COUNT TWENTY-SEVEN

VIOLATIONS OF THE RHODE ISLAND FALSE CLAIMS ACT R.I. Gen. Law §9-1.1-1 *et seq.*

False Claims for Adulterated Drugs

384. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

385. This is a claim for treble damages and civil penalties under the Rhode Island False Claims Act, R.I. Gen. Law §9-1.1-1 *et seq.*

386. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Rhode Island False Claims Act, R.I. Gen. Law §9-1.1-1 *et seq.*

387. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

388. By reason of Defendant's acts and omissions, Rhode Island has suffered substantial actual damages.

COUNT TWENTY-EIGHT

VIOLATIONS OF THE TENNESSEE FALSE CLAIMS ACT Tenn. Code Ann. §71-5-181 *et seq.*

False Claims for Adulterated Drugs

389. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

390. This is a claim for treble damages and civil penalties under the Tennessee False Claims Act, Tenn. Code Ann. §71-5-181 *et seq.*

391. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Tennessee False Claims Act, Tenn. Code Ann. §71-5-181 *et seq.*

392. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

393. By reason of Defendant's acts and omissions, Tennessee has suffered substantial actual damages.

COUNT TWENTY-NINE

VIOLATIONS OF THE TEXAS FRAUD PREVENTION ACT
Tex. Hum. Res. Code Ann. §36.001 *et seq.*

False Claims for Adulterated Drugs

394. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

395. This is a claim for treble damages and civil penalties under the Texas Fraud Prevention Act, Tenn. Tex. Hum. Res. Code Ann. §36.001 *et seq*.

396. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Texas Fraud Prevention Act, Tenn. Tex. Hum. Res. Code Ann. §36.001 *et seq*.

397. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

398. By reason of Defendant's acts and omissions, Texas has suffered substantial actual damages.

COUNT THIRTY

VIOLATIONS OF THE VERMONT FALSE CLAIMS ACT 32 V.S.A. § 632 *et seq.*

False Claims for Adulterated Drugs

399. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

400. This is a claim for treble damages and civil penalties under the Vermont False Claims Act, 32 V.S.A. § 632 *et seq*.

401. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Vermont False Claims Act, 32 V.S.A. § 632 *et seq*.

402. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

403. By reason of Defendant's acts and omissions, Vermont has suffered substantial actual damages.

COUNT THIRTY-ONE

VIOLATIONS OF THE VIRGINIA FRAUD AGAINST TAXPAYERS ACT Va. Code Ann. §8.01-216.1 *et seq.*

False Claims for Adulterated Drugs

404. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

405. This is a claim for treble damages and civil penalties under the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.*

406. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §8.01-216.1 *et seq.*

407. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

408. By reason of Defendant's acts and omissions, Virginia has suffered substantial actual damages.

COUNT THIRTY-TWO

VIOLATIONS OF THE STATE OF WASHINGTON FALSE CLAIMS ACT RCW §74.66.020 *et seq.*

False Claims for Adulterated Drugs

409. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

410. This is a claim for treble damages and civil penalties under the Washington False Claims Act, RCW §74.66.020 *et seq.*

411. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Washington False Claims Act, RCW §74.66.020 *et seq.*

412. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

413. By reason of Defendant's acts and omissions, Washington has suffered substantial actual damages.

COUNT THIRTY-THREE

VIOLATIONS OF THE WISCONSIN FALSE CLAIMS ACT Wis. Stat. §20.931, repealed July 12, 2015

False Claims for Adulterated Drugs

414. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

415. This is a claim for treble damages and civil penalties under the Wisconsin False Claims Act, Wis. Stat. §20.931, repealed July 12, 2015.

416. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Wisconsin False Claims Act, Wis. Stat. §20.931, repealed July 12, 2015.

417. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

418. By reason of Defendant's acts and omissions, Wisconsin has suffered substantial actual damages.

Filed Under Seal Pursuant to 31 U.S.C. § 3730(b)(2)

COUNT THIRTY-FOUR

VIOLATIONS OF THE CITY OF CHICAGO FALSE CLAIMS ACT Chicago §1-22-030 et seq.

False Claims for Adulterated Drugs

419. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

420. This is a claim for treble damages and civil penalties under the Chicago False Claims Act, Chicago §1-22-030 *et seq*.

421. By engaging in the conduct set forth herein, Defendant has knowingly caused to be presented false or fraudulent claims for approval in violation of the Chicago False Claims Act, Chicago §1-22-030 *et seq*.

422. The Government, unaware of the falsity of the records, statements, and claims caused to be made by Defendant, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

423. By reason of Defendant's acts and omissions, Chicago has suffered substantial actual damages.

COUNT THIRTY-FIVE

VIOLATION OF THE FEDERAL FALSE CLAIMS ACT 31 U.S.C. § 3729(a)(1)(B)

Defendant's Falsification of Records Certifying Compliance with the Current Good Manufacturing Practices

424. Relator realleges and incorporates by reference the allegations of all previous paragraphs as if restated herein.

425. 31 U.S.C. § 3729(a)(1)(B) states that "any person who . . . knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable under the Act.

426. By engaging in the conduct set forth above, Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims within the meaning of § 3729.

427. The Government, unaware of the falsity of the records, statements, and claims made or caused to be made by Defendant, paid and continues to pay the claims that would not be had the Government known of Defendants' respective failure to comply with the Current Good Manufacturing Practices paid but for Defendant's illegal conduct.

428. By reason of Defendant's acts, the United States and the FCA States have suffered actual damages.

COUNT THIRTY-SIX

VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT 31 U.S.C. § 3730(h)

RETALIATION AGAINST PLAINTIFF-RELATOR

429. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

430. 31 U.S.C. § 3730(h) provides, "(1) Any employee... shall be entitled to all relief necessary to make that employee... whole, if that employee is... discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against

in the terms and conditions of employment because of lawful acts done by the employee... in furtherance of, other efforts to stop one or more violations of this subchapter."

431. Defendant discriminated against Relator in the terms and conditions of employment when his lawful attempts to stop **Defendant** from submitting, or causing to be submitted, false claims and false records in support of false claims were met by Defendant with a retaliatory and pretextual refusal to promote **Relator** to multiple higher-paying positions , including Operations Lead, Operations Supervisor, and Technician II, for which he was qualified and for which he applied between January 25, 2016 and May 10, 2017.

COUNT THIRTY-SEVEN

VIOLATIONS OF THE MINNESOTA FALSE CLAIMS ACT Minn. Stat. §15C.145

RETALIATION AGAINST PLAINTIFF-RELATOR

432. Relator re-alleges and incorporates by reference the allegations contained in the preceding paragraphs as if fully restated herein.

433. Minn. Stat. §15C.145 (a) provides, "(1) An employee, contractor, or agent is entitled to all relief necessary to make that employee, contractor, or agent whole if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent, or associated others in

furtherance of an action under this chapter or other efforts to stop one or more violations of this chapter."

434. Defendant discriminated against Relator in the terms and conditions of employment when his lawful attempts to stop **Defendant** from submitting, or causing to be submitted, false claims and false records in support of false claims were met by Defendant with a retaliatory and pretextual refusal to promote **Relator** to multiple higher-paying positions , including Operations Lead, Operations Supervisor, and Technician II, for which he was qualified and for which he applied between January 25, 2016 and May 10, 2017.

IX. PRAYER FOR RELIEF

WHEREFORE, Relator, the United States, and the States are entitled to damages from Defendants in accordance with the provisions of 31 U.S.C. §§ 3729-3733, and Plaintiff/Relator requests that judgment be entered against Defendant, including that:

a. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.;*

b. Defendant pay an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus the appropriate civil penalty against Defendant pursuant to 31 U.S.C. §3729 (a)(1) and 28 C.F.R. § 85.5;

c. Plaintiff/Relator be awarded the maximum amount allowed as a Relator share pursuant to 31 U.S.C. § 3730(d);

d. Plaintiff/Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d);

e. Plaintiff/Relator be awarded be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to and available under the State FCA's;

f. Plaintiff/Relator be awarded relief, including lost earnings, double back pay, and attorneys' fees pursuant to the anti-retaliation provisions of Minn. Stat. §15C.145 and 31 U.S.C. § 3730(h);

g. Plaintiff/Relator be awarded the maximum amount allowed as a Relator share pursuant to the State FCAs.

h. The United States, FCA States, and Plaintiff/Relator be granted all such other relief as the Court deems just and proper.

Respectfully submitted and dated this 21st day of December, 2018.

Nola J. Hitchcock Cross
Wisconsin Bar No.1015816
(to be admitted Pro Hac Vice)
CROSS LAW FIRM, S.C.
Lawyer's Building
845 North 11th Street
Milwaukee, WI 53233
Telephone: (414) 224-0000
Facsimile: (414) 273-7055
Email: njhcross@crosslawfirm.com

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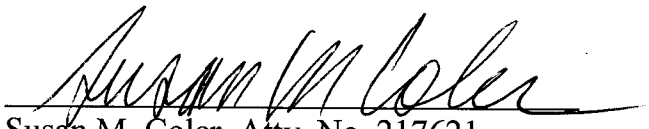
LOCAL COUNSEL:



Susan M. Coler, Atty. No. 217621
Nathaniel F. Smith, Atty. No. 397276
HALUNEN LAW
1650 IDS Center
80 South Eighth Street
Minneapolis, MN 55402
Telephone: (612) 605-4098
Facsimile: (612) 605-4099
coler@halunenlaw.com
smith@halunenlaw.com

ATTORNEYS FOR RELATOR-PLAINTIFF JOSEPH CALIGUIRE